CLINICAL INVESTIGATION PROGRAM REPORT

DWIGHT DAVID EISENHOWER ARMY MEDICAL CENTER FT GORDON, GA 30905

FY 97

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7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
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13. ABSTRACT *(Maximum 200 words)*
Subject report identifies the research activities conducted by Dwight David Eisenhower Army Medical Center investigators through protocols approved by the Institutional Review Committee for registration with the Department of Clinical Investigation during Fiscal Year 1997, and other know publications and presentations by the Dwight David Eisenhower Army Medial Center professional staff. A detail sheet of each protocol giving the objective, technical approach, and program is presented.

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CLINICAL INVESTIGATION

PROGRAM REPORT

01 October 1997

CONTROL SYMBOL: RCS MED-300 (R)

Department of Clinical Investigation
Dwight David Eisenhower Army Medical Center
Fort Gordon, Georgia 30905-5650

Foreword

The cover this year features Improvement (*Emendatio*). It is personified by a noble woman holding an auguring staff and a scroll in one hand as she gestures with the other. The staff and her nobility depict the necessity for authority to be able to improve upon institutions and general understanding. The scroll and the open book propped at her feet illustrate the necessity to be well versed in the current literature of the subject matter before attempting to improve upon it. Her open hand is a gesture of invitation to participate in the process. The figure in the background *fatto* is Julius Caesar surrounded by books as he contemplates the globe in an effort to improve the calendar. Obviously this is a bit anachronistic since the world was not generally regarded as round at the time of Julius Caesar.

The urge to improve upon things is a fundamental human instinct of noble and ancient origins. Since the ability to understand the true nature of things is beyond human grasp, we do none the less seek to refine our imperfect grasp upon the truth. We have to have a love of the truth to seek this goal and we need humility to recognize the difficulty of the task. Despite all of these proviso's, the urge to improve upon our understanding of things is a noble one and it needs to be encouraged.

The incorporation of this process into the formation of a physician reinforces the understanding that the process of becoming a healer of humanity requires the acquistion of many noble traits. The love of truth is one of these, as is the humility that our science is imperfect. Each patient we see is unique and may not fit into our generalizations and theories perfectly. A physician skilled in the process of perfecting his understanding should be more inclined to listen carefully to the patient before jumping to conclusions. Clinical decision making is the inverse process of applying general knowledge and theories to a particular case (deduction). Induction forms generalized theories from particularities that share common features. Both thought processes must be disciplined to find the truth or something close thereto.

Clinical Investigation in the military provides an opportunity for would be investigators to pursue improvements in knowledge or in the application of clinical skills to some unusual problems that might not exist in civilian medicine. The process can be developed and applied to operational issues and to unusual clinical settings to improve on the existing standard. A good case can be made that most significant discoveries have been made starting from an attempt to solve a particular problem or to improve on a process. The discipline of that focus seems to improve the outcome.

We at EAMC are finally on a course toward a major improvement in our physical plant. At long last ground has been broken for the two million dollar project to renovate and expand two buildings which will serve as vivarium and laboratory.

We are still some 15 to 18 months away from useful occupancy. Still this is the most concrete step forward in many years.

We have had two significant personnel turnovers this year. COL Dennis Runyan, DC has gone on to the USARAMC lab at Great Lakes being replaced by COL Stephen Cameron, DC. MAJ Kim Vlach, VC left to complete her residency at Ft. Detrich, MD and has been replaced by CPT Stephen Harvey, VC. Our two losses were stalwart members of our CI team and they are greatly missed. At the same time, we have great expectations of their replacements.

KENT M. PLOWMAN, PhD, MD
COL, MC
Chief, Clinical Investigation

UNIT SUMMARY - FISCAL YEAR 1997

A. Objective:

The objective of Clinical Investigation is to be responsible to the Deputy Commander for Clinical Services for providing the facilities and atmosphere of inquiry necessary to support and stimulate both basic and clinical medical investigation within DDEAMC.

B. Technical Approach:

All research, investigational, and training activities within the Department of Clinical Investigation are conducted under the guidance of R 40-38, AR 40-7, AR 70-18, and HSC Reg 40-23. Careful monitoring of all approved protocols is conducted in order to assure strict compliance with these applicable regulations.

C. Staffing:

NAME	RANK	MOS	TITLE
Plowman, Kent M	COL	61F	Chief
*Runyan, Dennis	COL	63F	Chief, Biometrics & Statistical Design
**Cameron, Stephen	COL	63F	Asst Chief
Niagro, Frank D	MAJ	71A	Microbiologist
Vlach, Kim D.	MAJ	64A	Veterinarian
Plaza-Garcia, Hamilton	CPT	71A	Microbiologist/Virologist
Lester, Joseph	1LT	71A	Microbiologist
Figueroa, Ronald J	SFC	91K40	NCOIC
Cawley, Eugene	SFC	91K40	Asst NCO
Vankluyve, Richard	SSG	91K30	Med Lab NCO
Smith, April	SGT	91T20	Sr Animal Care Specialist
Jaissle, James	SPC	91K10	Animal Care
Armendariz, Carlos	SPC	91K10	Medical Lab Specialist
Brethorst, Amy	PV2	91T10	Animal Care Specialist
Buxton, Thomas	GM12	00403	Microbiologist
McPherson, James C III	GS13	01320	Biochemist
Runner, Royce	GS11	00644	Medical Technologist
Best, Norma	GS9	00644	Medical Technologist
Brewer, Phyllis	GS7	00404	Histopathology Tech.
Ferguson, Phyllis	GS7	00303	Protocol Coordinator
Rouse, Sandra	GS5	00303	Asst Protocol Coordinator
Nelson, Manuela	GS5	00404	Biological Lab Tech
Vacant	GS4	00312	Clerk-Steno

*Pcs'd August 1997
**Filled position in September 1997

Officers: 4 authorized; 5 required; 6 assigned
Enlisted: 5 authorized; 9 required; 7 assigned
Civilians: 7 authorized; 13 required; 8 assigned

One third-party Geneva Foundation physician assistant in Clinical Investigation.
One third-party Geneva Foundation medical research assistant in Clinical Investigation.
One third-party Geneva Foundation clinical data coordinator in Clinical Investigation.
Two third-party FACT Foundation clinical research nurses in Clinical Investigation.

d. Funding:

TYPE	Fiscal Year 96	Fiscal Year 97
Civilian personnel to include benefits	356,644.19	319,289.36
Consumable supplies	121,121.78	98, 963.40
Civilian contracts to include consultants	1,515.00	14,729.41
TDY	9,597.86	831.00
Publications	659.00	1,236.70
Paper Presentations	8,430.25	8,690.92
CEEP	25,687.00	125,660.00
MEDCASE	455,987.00	102,421.00
Military	518,737.00	642,660.00
Total	1,555,814.00	1,314,481.70

GRANT FUNDING:

1. "Preventive Series: Role of the Nurse Practitioner", $295,634.00.
2. "Efficacy of Case Management in a Military Medical Center", $186,000.00
3. "Army Reserve Readiness: Health Behaviors/Workplace Factors", $197,859.00

CRADA FUNDING:

A Comparison of Two Impression Techniques for Accuracy of Occlusal Contacts $2,042.00.

Protocol Disposition FY 97

	Completed	Terminated	Ongoing to FY 98	
FY 90			1	
FY 91			4	
FY92		1	6	
FY 93	2		8	
FY 94	11	2	7	
FY 95	6	3	11	
FY 96	5	9	12	
FY 97	7		29	
TOTAL	31	16	78	(125)

Number of full-time residents and fellows (MC officers) trained at in FY 1997: 92 residents & 4 fellows
Number of residents and fellows held approved protocols in FY 1997: 38
Number of protocols these residents and fellows held in FY 1997: 20
Number of distinct residency and fellowship training programs represented above: 8 (Family Practice, Internal Medicine, General Surgery, Transitional Internship, Psychiatry, Child Psychiatry Fellowship, Joint Psychiatry/Family Practice, & Orthopaedic Surgery)
Number non-MC officer trainees holding approved protocols in FY 1997: 16
Number protocols held by non-MC trainees in FY 1997: 8
Number of distinct residency and fellowship training programs represented by Non-MC trainees: 6 (Oral Surgery, Periodontics, Endodontics, Prosthodontics, Clinical Psychology & Surgical Podiatry)
Number hospital staff members holding approved protocols in FY 1997: 29.
Number protocols held by hospital staff members in FY 1997: 41

Other training programs that use Clinical Investigation: Nurse Anesthesia, Health Care Administration, & Clinical Pastoral Care.

Scholarly products of the entire medical center:
Manuscripts actually published in FY 1997: Protocol pursuant: 0 Nonprotocol pursuant: 23
Abstracts published in FY 1997: Protocol pursuant: 1 Nonprotocol pursuant: 0
Platform presentations in FY 1997: Protocol pursuant: 10 Nonprotocol pursuant: 35

TABLE OF CONTENTS

EMERGENCY MEDICINE

NURSING

Psychiatry & Neurology

RADIOLOGY

SURGERY

SOUTHWEST ONCOLOGY GROUP

USA MEDDAC, FT JACKSON, SC

USA MEDDAC, FT BENNING, GA

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Code:

O - Ongoing
C - Completed
T - Terminated
W - Withdrawn
P - Published
PR - Presented

PUBLICATIONS

CLINICAL INVESTIGATION

Paustian PW, Murray MT, Akiyama DP, McPherson JC, III, and McPherson JC, JR: 20th Army Science Conference, Proceedings, vol 2, pp 717-721, 1996.

DENTAL ACTIVITY

Gronett PM, Driscoll CF, and Hondrum SO: Resiliency of surface-sealed temporary soft denture liners. Journal of Prosthetic Dentistry, Vol 77, No. 4, Apr 1997.

Clayton GH, Driscoll CF, and Hondrum SO: The Effect of Luting Agents on the Retention and Marginal Adaptation of the CeraOne Plant System. The International Journal of Oral & Maxillofacial Implants,, vol 12, No. 5, 1997.

Hondrum SO and Fernandez R Jr: Effects of Long-term Storage on Properties of an Alginate Impression Material. The Journal of Prosthetic Dentistry, Vol.77, No. 6, June 1997.

Hondrum SO and Fernandez R Jr: The Storage Stability of Dental Composite Resins: seven-year results. General Dentistry, July/August 1997.

Hondrum, SO and Fernandez R Jr: Contouring, Finishing, and Polishing Class 5 Restorative Materials. Operative Dentistry, 22, 30-36, 1997.

Johnson MA, Primack PD, Loushine RJ, and Craft DW: Cleaning of Endodontic Files, Part I: The Effect of Bioburden on the Sterilization of Endodontic Files. J Endodon, 23,32-4, 1997.

West LA,and Hansen BS: Allergic Reaction Following Insertion of a Pd-Cu-Au Fixed partial Denture: A Cliical Report. Journal of Prosthetic Dentistry, 6:144-8, 1997.

West LA, Loushine RJ, Cameron SM, Runyan DA, Joyce AP: Photoelastic Comparison of Stress Created Using Stainless Steel vs. Nickel Titanium Spreaders. J. of Endodon, 1997.

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Fitzpatrick DT: Primary Treatment of Pyoderma Gangrenosum With Hyperbaric Oxygen Therapy: A Case Report. Wounds, 9(3):103-106, 1997.

Fitzpatrick DT: The Applications of Hyperbaric Oxygen Therapy in Army Medicine. AMEDD Journal, 17-22. January/February 1997.

MEDICINE

Pehoushek JF, Heimer, WL: Solitary Facial Lesion. Sebaceous Adenoma in Association With Muir-Torre Syndrome (MTS). Archives of Dermatology. 133(1):98, 101-2, Jan 1997.

SURGERY

GENERAL SURGERY

Waddell BE, Calton WC Jr, Steinberg SR, Martindale RG: The Adverse Effects of Octreotide on Wound Healing in Rats. American Surgeon. 63(5):446-9, May 1997.

North JH: "The Role of Sentinel Node Biopsy in the Management of Malignant Melanoma". Oncology, 10:1237-1242,1996.

CARDIOTHORACIC

Brodie JE: The Intraaortic Balloon Pump. The Surgical Physician Assistant. July/August 1997.

ORTHOPAEDIC

Herzwurm PJ: Thigh Pain and Total Hip Arthroplasty: Scintigraphy With 2.5 Year Followup". Clinical Orthopaedics & Related Research. (336): 156-61. March 1997.

FAMILY & COMMUNITY MEDICINE

Jerant AF, Epperly TD: Fundamentals of Telemedicine. Military Medicine. 162(4):304-9, April 1997.

Johnson NA, Gore JR III: Atraumatic Pneumopericardium in a Full-term Newborn With Fetal Tachycardia. Journal of the American Board of Family Practice. 10(1):55-8, Jan-Feb 1997.

Jerant AF: Adenocarcinoma of the Uterine Cervix. Journal of the American Board of Family Practice. 10(1): 36-42, Jan-Feb 1997.

Jerant AF: "Fundamentals of Telemedicine". Military Medicine, 162-304-9, 1997..

Johnson NA: "The History of the Army Weight Standards". Military Medicine, Vol. 162, Aug 1997.

Johnson NA: "For Physicians Only". Courtlandt Forum, 10:64, 1997.

Cote L: "Women's Triage and Management Preferences for Cervical Cytological Reports Demonstrating ASCUS and LGSIL". Archives of Family Medicine, 6:348-53, 1997.

Johnson NA: "Penetrating BB Shot Head Wound in an Asymptomatic 9-Year Old Girl: The Ultimate Teaching Moment". Journal of the American Board of Family Practice, 10:125-30, Mar 1997.

NUTRITION CARE

King N: Perspectives on Nutritional Issues of Military Women. Selected Talks from the Forum on the Health of Women in the Military in Women's Health Issues, Volume 6 (6), 368-371, 1997.

PRESENTATIONS

CLINICAL INVESTIGATION

Czerwinski SE: "In Vitro Growth Inhibition of a Quinolone-Biphosphonate Drug, HP-ENC-6 (ENC6)". Presented at the Society of Armed Forces Medical Laboratory Scientists annual meeting in Spokane, Washington, Mar 1997.

DENTAL ACTIVITY

West LA: Endodontic Consultant for Two Year General Dentistry Program, Ft Bragg, NC 16-17 January 1997.

West LA: Endodontic Consultant, Dental Specialty Confernece, Sonthofen, Germany, 15-17 April 1997.

Bodey TE: Postert Research Presentation. A Retrospective Study Evaluating the Use of the Panoramic Radiograph in Endodontics, AAE Annual Meeting, Seattle, Washington, 6-11 May 1997.

Joyce AP: Poster Research Presentation. Photelastic Comparison of Stress Using Stainless Steel vs. Nickel Titanium Spreaders, AAE Annual Meeting, Seattle,Washington, 6-11 May 1997.

Apicella MJ: Oral Research Presentation. Comparisonof Three Obturation Techniques: An Evaluation of Root Fracture Resistance, AAE Annual Meeting, Seattle,Washington, 6-11 May 1997.

Angulo SJ: Oral Research Presentation. A Comparison of Nickel-Titanium Diffusion Across Root Dentin, AAE Annual Meeting, Seattle, Washington, 6-11 May 1997.

Shull CC: Oral Research Presentation. A Comparison of Nickel-Titanium vs Stainless Sttel Spreaders in Curved Canals, AAE Annual Meeting, Seattle, Washington, 6-11 May 1997.

EMERGENCY MEDICINE

Schwartz RB: "An Unusual Case of Lower Extremity Pain". Presented a the Annual Society of Academic Emergency Medicine CPC Competition, Washington, DC, May 1997.

FAMILY & COMMUNITY MEDICINE

Boland E: "Santa's Knee: A Painful Occupational Sequelae to Osgood-Schlatter's Disease". Presented at Uniformed Services Academy of Family Physicians XXII Annual Scientific Assembly, Norfolk, VA. March 1997.

Butcher J: "Cross-Country Skiing Injury Profile - Skating vs Traditional Technique". Presented at Uniformed Services Academy of Family Physicians XXII Annual Scientific Assembly, Norfolk, VA. March 1997.

Jenkins M: "Metastatic Melanoma: An Atypical Presentation". Presented at Uniformed Services Academy of Family Physicians XXII Annual Scientific Assembly, Norfolk, VA. March 1997.

Johnson NA: "Penetrating BB Shot Head Wound In An Asymptomatic 9-Year Girl: The Ultimate Teaching Moment". Presented at Uniformed Services Academy of Family Physicians XXII Annual Scientific Assembly, Norfolk, VA. March 1997.

Johnson NA: "Anterior T1 Vertebral Body-Tear Fracture Due to A Minor Bicycle Accident: Don't Delay That X-ray"! Presented at Uniformed Services Academy of Family Physicians XXII Annual Scientific Assembly, Norfolk, VA. March 1997.

Pfeifer A: "Recognizing and Managing Primary Hyperparathyroidism in Family Practice". Presented at Uniformed Services Academy of Family Physicians XXII Annual Scienftific Assembly, Norfolk, VA. March 1997.

NURSING

Schlachta L: "Telemedicine: The Information Age Enters the Home". Presented at Telemedicine Conference in Kearney, Nebraska, Oct 1996.

SURGERY

Raab MG: "Continuous Passive Motion After Rotator Cuff Repair". Society of Military Orthopaedic Surgeons Meeting, San Diego, CA, November 1996.

Jahnke AH: "The Biceps-Labral Complex: An Anatomic Study". Society of Military Orthopaedic Surgeons' Meeting in San Diego, CA, November 1996.

Malcolm JR: "Anterior Cervical Discectomy and Fusion Outcome in Patients With Dominant Axial Mechanical Cervical Spine pain". Society of Military Orthopaedic Surgeons' Meeting in San Diego, CA, November 1996.

Brucker WB: "Arthroscopic Examination and Debridement of the Thumb Metacarpophalangeal Joint". Society of Military Orthopaedic Surgeons' Meeting in San Diego, CA, November 1996.

Travis MT: "Thumb Basilar Joint Silicone Arthroplasty: An Intermediate Follow-up of a Lsrge Case Series". Society of Military Orthopaedic Surgeons' Meeting in San Diego, CA, November 1996.

Raab MG: "The Hand Diagram in Carpal Tunnel Syndrome". Society of Military Orthopaedic Surgeons' Meeting in San Diego, A, November 1996.

Legan J: "Synovial Impingement of the Radiocapitellar Joint: A Potential Cause of "Little League" Elbow". Society of Military Orthopaedic Surgeons' Meeting in San Diego, CA, November 1996.

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Raab, Michael G: "Continuous Passive Motion After Rotator Cuff Repair". Presented at the Society of Military Orthopaedic Surgeons' Meeting in San Diego, CA Nov 1996.

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Malcolm JR: "Anterior Cervical Disectomy and Fusion Outcome in Patients With Dominant Axial Mechanical Cervical Spine Pain". Presented at the Society of Military Orthopaedic Surgeons' Meeting in San Diego, CA Nov 1996.

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Travis MT: "Thumb Basilar Joint Silicone Arthroplasty: An Intermediate Follow-up of a Large Case Series". Presented at the Society of Military Orthopaedic Surgeons' Meeting in San Diego, CA Nov 1996.

Raab MG: "The Hand Diagram in Carpal Tunnel Syndrome". Presented at the Society of Military Orthopaedic Surgeons' Meeting in San Diego, CA Nov 1996.

Legan J: "Synovial Impingement of the Radiocapitellar Joint: A Potential Cause of "Little League" Elbow: Presented at the Society of Military Orthopaedic Surgeons' Meeting in San Diego, CA Nov 1996.

PSYCHIATRY

Correnti E, Davidson L, Cruser M, and Pace A: "Managing Change: What the Experiences of Career Soldiers Can Teach Us". Presented at the AMMED Behavioral Science Short Course, Tampa, Florida. May 1997.

Cruser M, Correnti E, and Davidson L: "Career Soldier's Perception of Sexual and Racial Discrimination in the Army. Presented at the AMMED Behavioral Science Short Course, Tampa, Florida. May 1997.

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ABSTRACTS

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Shono Y, Bori K, Wantanabe T, Terashita M, Brewer PD, and Pashley DH: "Effects of Surface Area on Resin-Enamel Bond Strength", IADR, 1977

McPherson JC, Jr., Murray KT, Stroebel, GG, Blankenship PR, Leibach, FH, and McPherson JC, III: Georgia Journal of Science, vol. 55, page 91, 1997. "Exton's Method for Urinary Albumin Quantitation Revisited".

Murray KT, Streobel GG, Leibach FH, Blankenship PR, McPherson JC, III and McPherson JC, Jr.: Georgia Journal of Science, vol. 55, page 92, 1997.

Blankenship PR, Saumweber M, Jr., Thevaos TG, Leibach FH, Mcpherson JC III, and McPherson JC Jr.: Georgia Journal of Science, vol 55, page 93, 1997. "Benzoic Aciduria in Non-Schizophrenic Patients."

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Paustian PW, McPherson JC III, Chuang AH, Akiyama DP, and McPherson JC Jr.: Academic Emergency Medicine, vol. 4, pp. 355-356, 1997. "Quantitation of Microcirculatory Blood Flow Enhancement by a Surfactant - One Mechanism of Action to Explain Improved Early Wound Healing by Surfactants."

McPherson JC Jr., McPherson, JC III, Murray MT, Paustian PW, Chaung AH, and Runner RR: Southeastern Surgical Congress Poster Session Abstracts, vol. 65, page 28, 1977. "Surface Active Agent for the Poloxamer Type Decreases Thermal Injury Edema: Comparison of Pre- and Post-Injury Treatment."

Paustian PW, McPherson JC III, Shahan MH, Fitzpatrick BD, Chuang AH, and McPherson JC Jr.: Southeastern Surgical Congress Poster Session Abstracts, vol. 65, page 15, 1997. "Pluronic F-68 Markedly Decreases Polymorphonuclear Cells in the Area of Incisional Wounds but Increased Wound Breaking Strength."

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Wright DJ, Smith TM, Stroebel GG, McPherson JC III, Runner RR and McPherson JC Jr.: "Poloxamer 407 Binding to and Protection of Red Blood Cells", Am Chem Soc Natl Mtg, Bk. Abstrs., 212, Pt. 1, CHED 141, 1996.

McPherson JC Jr, Smith TM, Stroebel GG, Chaung AH, Runner RR, and McPherson JC Jr.: "2,2'-Azobis (2-amidinopropane) Dihydrochloride Alters Hemoglobin from Freshly Hemolyzed Red blood Cells", S.E. Reg. Meeting Am. Chem. Soc., Abstr., SERMACS '96, Abstr. #144, 1996.

Murray K, Stroebel GG, McPheson JC III, Runner RR, and McPherson JC Jr.: "2,2'-Azobis(2-amidinopropane) Dihydrochloride Alters Hemoglobin from Freshly Hemolyzed Red Blood Cells", S.E. Reg. Meeting Am. Chem. Soc., Abstr., SERMACS '96, Abstr/ \3144, 1996.

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Paustian PW, Murray MT, Akiyama DP, and McPherson JC III: "Surfactants in Acute Battle care: Animal Model Studies". Procedings of the 20th Army Science Conference, vol 2, 717-721, 1996.

PSYCHIATRY

Cruser M, Correnti E, and Davidson L. "Sexual and Racial Discrimination in the Army". American Psychiatric Association Annual Meeting New Research Program and Abstracts, p.80. May 1997.

Correnti E, Davidson L, and Cruser M: "Career Soldiers' Attitudes Toward Homosexuals". American Psychiatric Association Annual Meeting New Research Program and Abstracts, p. 254. May 1997.

DETAIL

SUMMARY

SHEETS

DETAIL SUMMARY SHEET

Date: 20 Aug 97	Protocol: 96-4	Status: Completed
Title:	Nebulized Lidocaine to Attenuate the Vasopressor Response to Direct Laryngoscopy and Tracheal Intubation	
Start Date:		**Est. Compl. Date:**
Principal Investigator(s): Judith Bock, CPT(P), AN, MSN		**Facility:** Eisenhower Army Medical Center
Department/Service: Anesthesia		**Associate Investigators:** Jeffrey Ashby, CPT, AN Jody Borg, CPT, AN Jerry Cate, CPT, AN
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Completed

Study Objective: This experimental study will explore the effects of 120mg of nebulized lidocaine on the vasopressor response to direct laryngoscopy and tracheal intubation in ASA-I and ASA-II patients over 18 years of age presenting for various surgeries.

Technical Approach: Fifty-two ASA I and II patients presenting for various surgeries will be randomly divided into two groups. Group 0 will receive normal saline 3cc via nebulization and group 1 will receive 120mg nebulized lidocaine. All patients will receive midazolam, fentanyl, pentothal and rocurdnium according to a standardized induction protocol. The drug is given 10 minutes prior to intubation; other medications administered in order to time peak effect with intubation. Mean arterial pressure and heart rate are recorded before induction and at 30,60, and 180 seconds after laryngoscopy. This ends the period of data collection.

Number of Patients Enrolled During this Reporting Period: None.

Progress: Study completed.

Problems Encountered: None.

DETAIL SUMMARY SHEET

Date:	Protocol:	Status:
20 Aug 97	97-1	Completed
Title:	Relative Frequency of Adverse Neurological Effects After Subarachnoid Block Using 5% Lidocaine. A Retrospective Telephone Survey Study.	
Start Date: Oct 96		**Est. Compl. Date:** Sep 96
Principal Investigator(s): John Canady, CPT, AN		**Facility:** Eisenhower Army Medical Center
Department/Service: Anesthesia		Associate Investigators: Ronald Cashion, CPT, AN Mary Hargrove, CPT,AN Anita Ganz, CPT, AN Michael Hoerr, CPT, AN
Key Words: Subarachnoid; Perineal		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Completed

Study Objective: To determine if adverse neurological effects after subarachnoid bloc (SAB) anesthesia occur more frequently with 5% lidocaine use than they do with 0.75% bupivacaine or 0.5% tetracaine.

Technical Approach: A retrospective telephone survey approach will be used to assess if patients have experienced any effects such as decreased perineal sensation, bladder dysfunction, lower back, buttocks, and leg pain, lower extremity sensory deficit, lower extremity weakness or bowel dysfunction. Study samples will be drawn from patients at two large Army medical centers and two large Army community hospitals in the southeastern US.

Progress: Data collection completed. Currently performing data analysis. **Study Completed.**

DETAIL SUMMARY SHEET

Date:	Protocol:	Status:
8 Jun 97	94-53	Terminated
Title:	Training for Department of Clinical Investigation and Veterinary Services Personnel in Medical, Surgical, and Emergency Care and Treatment, and Laboratory, Pathology, and Radiologic Procedures for Various Laboratory Animal Species	
Start Date:		**Est. Compl. Date:**
Principal Investigator(s): Kim Vlach, CPT, VC		**Facility:** Eisenhower Army Medical Center
Department/Service: Clinical Investigation		**Associate Investigators:** COL James Elmore, DVM
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Terminated

Study Objective: To provide training in routine and emergency medical surgical, laboratory, pathology and radiology procedures for personnel of the Department of Clinical Investigation and Veterinary Services, using government owned animals.

Technical Approach: Use colony animals only for procedures which do not require euthanasia. A variety of animal use protocols require that the personnel providing this support have some measure of proficiency and competency in the performance of tasks associated with conducting these studies. It is necesary for personnel to learn new tasks, new methods, new procedures, or combinations thereof. It is necesary for personnel to practice skills which they already possess to establish a means for utilizing available animal resources to obtain this required training.

Subjects enrolled to date: 4

Progress: None. Protocol terminated and resubmitted in July 1997.

DETAIL SUMMARY SHEET

Date: 5 May 97	**Protocol:** 94-59	**Status:** Terminated
Title:	A New In Vitro Model Using Laboratory Mouse (Mus Musculus) Osseous Cells and an In Vivo Animal Model (Rattus Norvegicus) for Evaluating Biocompatibility and Cytotoxicityof Dental Impression Materials	
Start Date:		**Est. Compl. Date:**
Principal Investigator(s): Dennis A Runyan, LTC, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Clinical Investigation		**Associate Investigators:** LTC Benjamin S. Hanson, ED LTC Stephen M. Cameron, DE COL David M. Lewis, DE MAJ David W. Craft, MS MAJ Steven W. Tobias, MS, DVM
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Terminated

Study Objective: Determine if the use of TGF-B & PDGF might enhance second healing.

Technical Approach: Fibroblast are grown in vitro and then cultured with TGFB or PDGF.

Progress: None.

Problems encountered: Samples lost. Study terminated.

DETAIL SUMMARY SHEET

Date: 8 Mar 97	Protocol: 96-20	Status: Closed
Title:	The Effect of a Novel Quinolone-bisphosphonate Drug in the Rat Tibial Model for Osteomyelitis (Rattus norvegicus)	
Start Date:		**Est. Compl. Date:**
Principal Investigator(s): Thomas Buxton, PhD		**Facility:** Eisenhower Army Medical Center
Department/Service: Clinical Investigation		**Associate Investigators:** Kent M. Plowman, COL, MC Kim D. Vlach, CPT, VC Dennis A. Runyan, COL, DE
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Closed

Study Objective: To examine a novel compound of an antibiotic with efficacy against Staphylococcus aureus in osteomyelitis. It is linked with a bisphosphonate to bind the antibiotic to the bone area and to inhibit the osteoclast which is the cell thought to be important in the host body to perpetuating the infection once established. The compound will be compared to the parent compounds alone and in combination in their effect on eradicating the infection in the rat tibia.

Technical Approach: This study will use HP-ENC-6 in an experimental rat osteomyelitis model. The model was used previously to measure aspects of both acute and chronic osteomyelitic disease. Treatment regimens will begin 7 days post surgery. Treatment will continue for 14 days (ending at day 21). Drugs will be given by the PI or his assistant using intraperitoneal (IP) injection with disposable tuberculin microsyringes with 25 gauge or smaller needles. Twelve rats are included in each of five treatment groups (60 rats total). Pain category is D.

Progress: Replaced ENC-6 with a new drug ENC 22, strain SMH replaces Cowan. HP-ENC-6 treatment, completed, MIC=2ug/ml, Cowan 1; GC-MS spectra of drug; Hydroxyapatite binding studies (in vitro).

Number of animals enrolled: 30

Problems Encountered: Infection (day 7 to 21) self resolved. Cowan 1 strain less virulent than assumed. Drug insolubility and IM injection were difficult.

DETAIL SUMMARY SHEET

Date:	Protocol:	Status:
29May 97	97-38	Ongoing
Title:	Veterinary and Techniques Trainingl Protocol for Authorized Personnel Utilizing Various Laboratory Animal Species.	
Start Date: Jul 1997		**Est. Compl. Date:**
Principal Investigator(s): Frank Niagro, MAJ, MC		**Facility** Eisenhower Army Medical Center
Department/Service: Clinical Investigation		**Associate Investigators:** Manuela Nelson, Sr Lab Tech April Smith, SGT, NCOIC, Lab Animal Spt Svc
Key Words: Heat Stroke, Pluronic polyols		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Ongoing

Study Objective: To train investigators and LASS personnel to perform both routine and emergency safe animal handling techniques, medical, surgical, pathological, and radiological procedures.

Technical Approach: Procedures to be performed will depend on personnel or investigator training requirements. Training topics may include, but not be limited to: handling and restraint techniques; blood sampling; collection, handling and preservation of tissue and fluid specimens; administration of medications to include both parenteral and injectable routes; anesthetic principles, induction, monitoring, and emergencies; arterial and venous cut-downs; catheter placement; fluid therapy; suture techniques; diagnostic tests, cardiopulmonary resuscitation; and radiographic and fluoroscopic techniques.

Progress: None. Protocol recently approved.

DETAIL SUMMARY SHEET

Date: 9 Sep 97	Protocol: 94-49	Status: Closed
Title:	Women's Health Care Isues: The Incidence of Localized Osteitis in Female Soldiers Using Norplant Contraceptives	
Start Date:		**Est. Compl. Date:**
Principal Investigator(s): Jim Strider, LTC, DE		**Facility:** Tingay Dental Clinic
Department/Service: Dental		**Associate Investigators:** COL Ricney Newhouse, DE MAJ Jim Duke, DE LTC Benjamin Hanson, DE LTC Dennis Runyan, De James McPherson, III, PhD
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Closed

Objective: To compare and evaluate post-operatiave localized osteitis following molar extractions among patients who are currently bieng administered Levonorgstrel (NOR-PLANT) with the female population who are taking no systemic birth control.

Number of patients enrolled: 32

Progress: We retried to contact the patients on the lists and through other avenues available. Sent e-mail messages. We are in the middle of processing all the data we have collected to complte this study.

Problems Encountered during this period: Due to the limitation of doing the study only on military and eligible family members , it was difficult to get more patients enrolled. We have exhausted the resources available to us. Study closed.

DETAIL SUMMARY SHEET

Date:	Protocol:	Status:
28 May 97	94-65	Completed
Title:	Women's Health Care Issues: The Effects of Estrogen Levels on Osseointegration of Dental Implants	
Start Date:		**Est. Compl. Date:**
Principal Investigator(s): Michael F. Cuenin, LTC, MC		**Facility:** Tingay Dental Clinic
Department/Service: Dental		**Associate Investigators:** COL Michael A. Billman, DE LTC Larry Kudryk, DE COL Richney F. Newhouse, DE LTC Dennis A. Runyan, DE LTC Stephen M. Cameron, DE
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Completed

Objective: To compare and evaluate the success of dental implants in a female soldier population. The aim of the study is to determine if an association exists between sex hormone levels and the osseointegration of dental implants.

Technical Approach: the patient population will be divided into three groups. The first group will consist of patients who are presently using systemic birth control. The second patient population will consist of individuals not employing systemic birth control. The third group will consist of male soldiers who will be enrolled in the study as a negative control.

Number of subjects enrolled: 30

Progress: All implants have been placed. Study completed.

Problems encountered: None.

DETAIL SUMMARY SHEET

Date:	20 May 97	**Protocol**	94-74	**Status**	Completed
Title:	The Proteolytic Activity of Porphyromonas gingivalis and Prevotella intermedia Against Heme-binding Plasma Proteins				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Michael Billman, COL, DE			**Facility:** Tingay Dental Clinic		
Department/Service: Dental			**Associate Investigators:** Geoffrey R. Tompkins, PhD, MCG COL Benjamin S. Hanson, DE MAJ David W. Craft, MS		
Key Words:					
Accumulative MEDCASE cost:			**Periodic Review Results:** Sep 97, Completed		

Objective: To determine if P. gingivalis and P. intermedia possess an enzyme (proteolytic) that assists in the acquisition of heme even in the presence of heme-binding proteins that would seem to resist the acquisition of heme by the pathogens and if an enzyme (proteolytic) specific for heme-binding proteins exists, which protease inhibitors can be selectively added to the assay in order to decrease or eliminate the viability of the enzyme.

Technical Approach: The enzymatic activity of these bacteria will be tested (in vitro) against dialyzed whole human plasma. During incubation of the bacteria with plasma, samples will be separated and analyzed. The investigator has chosen to study hemopoxin and haptoglobin to test the possibility of P. gingivalis and P. intermedia break apart these hemopexin-heme and haptoglobin-hemoglobin complexes. Once these complexes are separated the bacteria may uptake and use the free heme. The investigator will analyze the enzymatic activity of these bacteria in order to assess this possibility and analysis will be made as to the potential chemical inhibitors of these enzymes.

Number of subjects enrolled for the reporting period: N/A

Progress: Study Completed.

Date:	20 Aug 97	**Protocol**	94-76	**Status**	Completed
Title:	A Comparison of Two Impression Techniques for Accuracy of Occlusal Contacts				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Stephen M. Cameron, COL, DE			**Facility:** Tingay Dental Clinic		
Department/Service: Dental			**Associate Investigators:** COL James C. Hughbanks, DE COL Max L. Gaston, DE LTC David Reid, DE		
Key Words:					
Accumulative MEDCASE costs:			**Periodic Review Results:** Sep 97, Completed		

Objective: To investigate and compare the accuracy of interocclusal relationships of articulated casts from a closed mouth impression technique and a full arch conventional impression technique.

Technical Approach: Interocclusal records made with Blue-Mousse will be used for the evaluation. Each point of occlusal contact on the intraoral record will be visually identified and selected if it's thin enough to transmit light. An interocclusal record will be made from the articulated casts of each of the two impression techniques. For each of these points, the other two registrations will be evaluated to see if there is a corresponding point or not.

Progress: Research completed. Presented at the 1996 meeting of the American College of Prosthodontists. Accepted for publication in J. Prosthet Dent in August or September.

DETAIL SUMMARY SHEET

Date:	20 May 97	**Protocol**	94-78	**Status**	Closed
Title:	The Effects of Tetracyclines on Murine Bone Cell Cultures (Mus Musculus)				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Gary D. Swiec, MAJ, DE			**Facility:** Tingay Dental Clinic		
Department/Service: Dental			**Associate Investigators:** COL Michael A. Billman, DE COL Benjamin S. Hanson, DE LTC Val L. Kudryk, DE CPT Kim D. Vlach, MS, DVM		
Key Words:					
Accumulative MEDCASE cost:			**Periodic Review Results:** Sep 97, Closed		

Objective: To determine the effect of varying doses of tetracycline on mouse bone cells grown in a dish.

Technical Approach: The mice will provide an immature supply of bone cells which mimics the situation found around diseased human teeth during surgery, just prior to placement of the tetracycline/graft mixture. The investigator will harvest and grow bone cells from mice in 12-well plastic tissue culture plates. Cell cultures grown both with and without tetracycline will be followed for 20 days. Cell cultures will be observed microscopically for growth. Specific activity of bone producing cells, or osteoblasts, will be analyzed by staining for alkaline phosphates activity. Growth media cell cultures will be sampled, stored at 70 degrees C and assayed for cytokine and osteocalcin presence. The results of this study will aid in the treatment of soldiers with periodontal disease.

Progress: Study closed.

DETAIL SUMMARY SHEET

Date:	20 Aug 97	**Protocol**	95-43	**Status**	Terminated
Title:	Effects of Nicotine on Expression of B Cell Leukemia/Lymphoma - 2 Proto-Oncogene (BCL2), P-53 Tumor Suppressor Gene and cFOS Proto-Oncogene Messenger RNA in Murine (Mus Musculus) Osteoblast Cells.				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Stephen J. Rouse, MAJ, ED			**Facility:** Tingay Dental Clinic		
Department/Service: Dental			**Associate Investigators:** Michael A. Billman, COL, DE Michael F. Cuenin, LTC, DE Val L. Kudryk, LTC, DE		
Key Words:					
Accumulative MEDCASE cost:			**Periodic Review Results:** Sep 97, Terminated		

Objective: To determine the levels of three cell cycle regulators (BCL2,P-53 and cFOS) in bone forming cells during the phases of growth and in response to a chemical insult (nicotine).

Technical Approach: Mice are needed to supply an immature supply of bone cells that mimics the situation found around diseased human teeth. Bone cells will be harvested and grown from mice in plastic tissue culture plates.

Number of subjects enrolled for the reporting period:

Progress: Osteoblast harvest and initial characterization of cells.

Problems Encountered: Expression of BCL_2 was not found in preliminary runs and further investigation has ceased.

DETAIL SUMMARY SHEET

Date:	20 May 97	**Protocol**	95-44	**Status**	Ongoing
Title:	Evaluation of the Effects of Transforming Growth Factor Beta and Divinyl Benzene Beads on Osseous Regeneration in Rat Calvaria (Rattus Norvegicus)				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Paul O. Francis, MAJ, DE			**Facility:** Tingay Dental Clinic		
Department/Service: Dental			**Associate Investigators:** Michael F. Cuenin, LTC, DE James C. McPherson, III, Ph.D		
Key Words:					
Accumulative MEDCASE cost:			**Periodic Review Results:** Sep 97, Ongoing		

Objective: To determine the effect of Transforming Growth Factor Beta (TGF-B) and Divinyl Benzene beads (DVBb) on osseous regeneration in rats.

Approach: Animals will be stabilized and isolated for 7 days prior to beginning the protocol. Following the surgical procedures, the animals will be observed for any signs of pain or distress.

Number of subjects enrolled for the reporting period: N/A

Progress: Completed necropsy and obtained data on all specimens. Histomorphometry and densitometry ongoing. Completing wax and presented 2 lectures at MCG on the results. An updated lit search and copies of appropriate articles for thesis have been obtained.

Problems encountered: No technical problems - some problems with analyzing data but have support from committee. Study remains open.

DETAIL SUMMARY SHEET

Date:	20 Aug 97	**Protocol**	95-46	**Status**	Terminated
Title:	The Effects of Blood Sugar Levels on Osseous Regeneration in Sprague-Dawley Rats (Rattus Norvegicus) Grafted with Allograft.				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): Gregory A. Blythe, MAJ, DE		**Facility:** Tingay Dental Clinic			
Department/Service: Dental		**Associate Investigators:** James C. McPherson, III, Ph.D Michael A. Billman, COL, DE Michael F. Cuenin, LTC, DE Val L. Kudryk, LTC, DE			
Key Words:					
Accumulative MEDCASE cost:		**Periodic Review Results:** Sep 97, Terminated			

Objective: To determine the effect of varying blood sugar levels on bone regeneration using allografts in rats.

Technical Approach: This study will look at bone regeneration in rats that have elevated blood glucose levels.

Number of subjects enrolled for the reporting period: N/A

Progress: None. IRB voted to terminate this study and resubmit with new approach because of problems controlling blood glucose levels and resulting hign mortality rates prior to any surgical manipulations.

DETAIL SUMMARY SHEET

Date: 20 Aug 97	**Protocol:** 96-22	**Status:** Terminated
Title:	A Comparative Analysis of the Cement Seal at the Margins of Cast Restorations Following Removal of the Excess Cement at Different Time Intervals.	
Start Date: April 1996		**Est. Compl. Date:**
Principal Investigator(s): Ashton C. Trier, DDS		**Facility:** Tingay Dental Clinic
Department/Service: Dental		**Associate Investigators:** Merle H. Parker, DOL, DS Stephen M.Cameron, COL, DC Max L. Gaston, COL, DC
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Terminated

Study Objective: To evaluate the integrity of a margin's cement seal as influenced by the time of the excess cement removal, the marginal opening, and type of cement.

Tecnhical Approach: The powder and liquid of each cement mixed according to the manufacturers' instructions. The mixed cement will be placed on a plate and the opposing plate positioned as previously indicated. A load of 147 newtons (15kg) shall be applied vertically on the top plate[14]. The excess cement will be removed with an explorer, according to the predetermined time intervals. Each cement will be tested 10 times. Each mix of cement will be applied to the sample plates and the excess cement removed before another mix is initiated. The sample will be set aside to be observed under the microscope at a later time. The primary investigator will prepare all of the test specimen and perform each of the mixes.

Number of subjects enrolled: NA

Progress: None, project terminated due to technical difficulties.

DETAIL SUMMARY SHEET

Date: 20 Aug 97	**Protocol:** 96-23	**Status:** Completed
Title:	Etchant Effects on Bond Strengths of Empress	
Start Date: April 1996		**Est. Compl. Date:**
Principal Investigator(s): Stephen M. Cameron, COL, DE		**Facility:** Eisenhower Army Medical Center
Department/Service: Dental Activity		**Associate Investigators:** Max L. Gaston, COL, DDS Merle H. Parker, COL, DDS Richard J. Windhorn, MAJ, DDS
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Completed

Study Objective: The purpose of this study is to determine whether there is a difference in bond strengths of Empress ceramic when different etchants are applied for differing time intervals.

Technical Approach: The protocol involves taking 90 samples of Empress ceramic, and subjecting 30 samples to Strip-It, 30 samples to 4.5% Hydrofluoric Acid, and 30 samples to 1.23% APF Gel. the duration of contact with each etchant will be varied. Ten samples of Empress will be used to test each time interval. The time intervals will be: 1/2 the manufacturer recommended time, then the manufacturer recommended time, and twice the manufacturer recommended time.

Number of Subjects Enrolled:

Progress: Study completed, submitted for publication.

Problems Encountered: None.

DETAIL SUMMARY SHEET

Date: 20 Aug 97	Protocol: 96-26	Status: Completed
Title:	Measuring the Effectiveness of a Disinfectant on Bacterial Contamination of a Tissue Conditioner and a Soft Reline Material	
Start Date: May 96		**Est. Compl. Date:**
Principal Investigator(s): Stephen M. Cameron, COL, DE		**Facility:** Eisenhower Army Medical Center
Department/Service: Dental Activity		**Associate Investigators:** Max L. Gaston, COL, DE Merlel Harry Parker, COL. DE Norma Best, BS, Medical Technologist
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Completed

Study Objective: To determine whether routine disinfection procedures with a chlorine dioxide solution to common denture liners (COE Soft <CS> and Coe Confort <CC>) effectively reduces bcterial and fungal contamination of the material.

Technical Approach: Fifty-six disinfected samples will be rinsed with normal sterile saline to remove residual disinfectant. The acrylic side will be cut 1mm, then broken in half with a pair of flame sterilized pliers. The reline material will be sectioned from the acrylic side through the reline material with a sterile scapel blade. Ten samples from each group will be placed into fifty 50ml centrifuge tubes containing 15mls of culture medium. Each tube will be vortexed for 1 minute and then allowed to stand for 9 minutes. Two samples from each group will be examined under the scanning electron microscope for presence of bacteria.

Number of subjects enrolled: None.

Progress: Study completed.

DETAIL SUMMARY SHEET

Date: 15 Sep 97	**Protocol:** 97-3	**Status:** Ongoing
Title:	Effects of Mechanical Stress and Demineralized Freeze-Dried Bone Allograft on Cultured Murine Mus musculus Osteoblasts	
Start Date: Oct 96		**Est. Compl. Date:**
Principal Investigator(s): Richard a. Nichols, Jr., MAJ, DMD		**Facility:** Eisenhower Arny Medical Center
Department/Service: Dental		**Associate Investigators:** Michael F. Cuenin, LTC, DDS Frank D. Niagro, MAJ, PhD
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Ongoing

Study Objective: To culture murine osteoblasts from mouse pup calvaria in the presence of demineralized freeze-dried bone (DFDBA) that has varying levels of remaining mineral (calcification).

Technical Approach: Newborn (2-day old mouse pups will be euthanized by Laboratory Animal Support Service by cervical dislocation, and the calvaria will be obtained immediately as the origin for osteoblast cells. Approximately one hundred calvaria will be collected and placed in a solution of phosphate buffered saline and a digestive enzyme to dissociate cells from the bone matrix. Four sequential collagenase digests will be performed. Buffy coats will be combined from four digests, counted, suspended in alpha-Minimum Essential Media for subsequent use.

Progress: Osteoblast (Murine pups) harvests completed (3 done). Pilot studies concluded. Culturable cells frozen for further experiments. RT-PCR pilot project initiated.

Problems Encountered: None.

DETAIL SUMMARY SHEET

Date: 1 Oct 97	Protocol: 97-4	Status: Ongoing
Title:	The Effects of Varying Degrees of Allograft Decalcification on Cultured Murine (Mus Musculus) Osteoclast Cells	
Start Date: Nov 96		**Est. Compl. Date:**
Principal Investigator(s): Robert W. Herold, CPT, DE		**Facility:** Eisenhower Army Medical Center
Department/Service: Dental		**Associate Investigators:** Michael F. Cuenin, DMD Frank D. Niagro, MAJ, MS
Key Words: Euthanasia, osteoblast, osteoclast		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Ongoing

Study Objective: To measure pit formation and expression of osteoclast cell marker genes to provide a more thorough evaluation of the effect DFDBA on osteoclasts. The hypothesis is that a certain level (%) of calcium mineral content will induce eitehr maximal or minimal osteoclast proliferation and activity.

Technical Approach: After cervical dislocation of newborn mice, calvaria will be obtained as the source for the initial osteoblast cell cultures. The femurs will be collected from each mouse pup. A co-culture of osteoblast and marrow cells from the femur of thelaboratory mouse will be used to differentiate monocytes to osteoclasts. This co-culture will be placed in alpha-MEM (minimum essential medium) with 10% FBS (fetal bovine serum) at ph 7.5 with 10^{-8} M $1,25(OH)_2D_3$. Human decalcified freeze dried bone allogaft will be prepared to three specific levels of calcium mineral content (degree of mineralization). The control group will consist of cells incubated in 10cm culture dishes with 4 ml of 2% collagen (type I) gel matrix.

Progress: Reasonable progress. Surgeons are using the long bones of the farm pigs for ATLS training.

Problems encountered: No significant problems.

DETAIL SUMMARY SHEET

Date: 19 Sep 97	Protocol: 97-5	Status: Ongoing
Title:	The Effects of Varying Degrees of Allograft Decalcification on Cultured Murine (Mus Musculus) Osteoblast Cells	
Start Date: Nov 96		**Est. Compl. Date:**
Principal Investigator(s): William T. Burns, MAJ, DE		**Facility:** Eisenhower Army Medical Center
Department/Service: Dental		**Associate Investigators:** Michael A. Billman, DDS, MS Michael F. Cuenin, DMD Frank D. Niagro, MAJ, MS
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Ongoing

Study Objective: To search for the specific level (%) of calcium mineral content in DFDBA which will induce maximum proliferation, matrix maturation, and mineralization by mouse osteoblasts in vitro.

Technical Approach: Osteoblasts will be obtained from the mouse pup calvaria. After cervical dislocation, one hundred calvaria will be harvested and placed in a solution of phosphate buffered saline (PBS) and a digestive enzyme (0.05% type 1 collagenase) to detach cells from the bone matrix. Cells will be washed and separated by density gradient (Ficoll-Paque). Buffy coats will be combined from the digests, counted, suspended in alpha-Minimum Essential Media (a-MEM) supplemented with a 10% heat inactivated fetal bovine serum (FBS) and a 10-8M 1,25 dihydroxy vitamin D3 and grown out to the third passage under incubation conditions of 37°C and 5% carbon dioxide with media changes every 4 days. Cells will be frozen for subsequent use.

Progress: Proliferation pilot study initiated. Osteoblast harvest initiated.

Problems encountered: Difficulties placing DFDBA in media, resolved.

DETAIL SUMMARY SHEET

Date:	19 Sep 97	**Protocol**	97-6	**Status**	Ongoing
Title:	The Effects of Metronidazole on Murine (Mus Musculus) Bone Cell Culture.				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): Stephen J. Rouse, DMD		**Facility:** Eisenhower Army Medical Center			
Department/Service: Dental		**Associate Investigators:** Michael F. Cuenin, DMD Frank D. Niagro, PhD			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Ongoing			

Study Objective: To culture osteoblasts from mouse calvaria, subject them to five different concentrations of metronidazole (5,20,50,200 and 500ug/ml), and to measure the effect of each dose on the osteoblast's ability to differentiate.

Technical Approach: Calvaria will be obtained from newborn mice after cervical dislocation as the origin of the osteoblast cells. One hundred calvaria will be collected and placed in a solution of phosphate buffered saline (PBS) and a digestive enzyme (0.05% type 1 collagenase) to dissociate cells from bone matrix. Four sequential collagenase digests will be performed. Cells will be washed and separated by density gradient (Ficoll-Paque). Buffy coats will be combined from the four digests, counted, suspended in alpha-Minimum Essential Media (a-MEM) supplemented with 10% heat inactivated fetal bovine serum (FBS) abd 10^{-8}M 1,25 dihydroxy Vitamin D_3 and grown out to the third passage under incubation conditions of 37° C and 5% carbon dioxide with media changes every 4 days. The cells will then be frozen for subsequent use.

Progress: Isolation and amplication of mRNA expressed by osteoblasts at varying metronidacole concentrtion (in media)

Problems encountered: None.

DETAIL SUMMARY SHEET

Date: 9 Sep 97	Protocol: 97-23	Status: Ongoing
Title:	The Identification of Insulin Responsive Genes in Bone Cells	
Start Date:		**Est. Compl. Date:**
Principal Investigator(s): Gregory A. Blythe, LTC, DE		**Facility:** Eisenhower Army Medical Center
Department/Service: Dental		**Associate Investigators** James C. McPherson, III, PhD Frank D. Niagro, PhD Michael F. Cuenin, DMD
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Ongoing

Study Objective: To determine which genes, in an osteoblast culture from mouse calvaria, are responsive to insulin at 30 minutes and 120 minutes. Once these genes are detected, this information should then provide some indication concerning the genes to examine in the in vivo rat mode. The null hypothesis is that insulin will not have an effect on the evaluated genes.

Technical Approach: In vitro Phase: Murine osteoblasts, revived from frozen stocks, will be plated in replicate wells per routine methods in this laboratory. Expression of several genes including the jun and fos family of transcription factors and bone phenotype markers such as osteocalcin will be analyzed by RT-PCR amplification and agarose gel electrophoretic analysis.

In Vivo Phase: Four groups of 3 rats each will be used. The rats will be housed for one week prior to the start of the project to allow for acclimatization. RNA will be extracted from frozen femurs, muscle and thyroid glands and frozen. Thyroid RNA may be analyzed for expression of PTH and calcitonin genes

Progress: Rats have been sacrificed. Identification of insulin responsive bone cell genes is now being completed. Next procedure is to sequence additional bards seen in the osteocalcin gene. Study remains open.

DETAIL SUMMARY SHEET

Date:	**9 Sep 97**	**Protocol**	94-77	**Status**	Closed
Title:	Emergency Medicine Trauma Lab (Sus Scrofa)				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): Daniel Cruser, CPT, MCharm. D.		**Facility:** Eisenhower Army Medical Center			
Department/Service: Emergency Medicine		**Associate Investigators:** Richard B. Schwartz, MAJ, MC Ivy Shuman, MD Brendan O'Hara, MD F.P. Craig Miner, MD Jeffrey Brasfield, CPT, MS Connier Lavier-Reynolds, CPT, MC			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Closed			

Study Objective: The objective of this protocol will be basic proficiency training of physicians (interns and residents) working in the Emergency Department with necessary life-saving procedures and as a refresher proficiency training of staff health care providers. This lab will also reinforce skills learned in the ATLS course.

Technical Approach: Each session will consist of up to four interns/residents and will utilize one pig. Several standard procedures will be performed on the pig allowing maximal use of each pig when training physicians. The estimated number of procedures to be taught is up to 48 students per year during 12 sessions per year.

Number of subjects enrolled for the reporting period. None.

Progress: None. Study closed.

DETAIL SUMMARY SHEET

Date:	20 Aug 97	**Protocol**	96-24	**Status**	Ongoing
Title:	Mobile Emergency Medicine Information System Study				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Richard B. Schwartz, MAJ, MC.			**Facility:** Eisenhower Army Medical Center		
Department/Service: Emergency Medicine			**Associate Investigators:** Goran M. Djuknic, PhD Diane Y. Hou, MS Andre S. Smith		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 97, Ongoing		

Study Objective: This study will investigate the quality of collecting, acccessing, or documenting patient information by field medical personnel (emergency medical) technicians/medics/paramedics can be improved through use of a field medical computer/communication system. It will also investigate whether such an information system would likely improve the quality of patient care through the information that it provides to the field medical personnel and through the improved speed, accuracy, and completeness with which information collected in the field is provided to the hospital emergency department or trauma center.

Technical Approach: Subjects will be patients transported by the DDEAMC Ambulance Service in the Augusta area. Because the field medical devices are intended to be used with any type of patient requiring trauma and because we see no risks in using this equipment that are peculiar to any particular type of subject, there are no selection criteria for the study except that the patients be involved in a medical transport under the auspices of the DDEAMC.

Number of subjects enrolled this reporting period: None.

Progress: System upgrades are being accomplished to enter second phase of study.

Problems encountered: None.

DETAIL SUMMARY SHEET

Date:	11 Sep 97	**Protocol**	97-45	**Status**	Ongoing
Title:	Incidence of Akathisia in Adult Patients Receiving Compazine by Either IV Push or IV Infusion for the Treatment of Uncomplicated Migraine in the Emergency Department				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Richard B Schwartz, MAJ, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Emergency Medicine			**Associate Investigators:** John L. Pearson, MD		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 97, Ongoing		

Study Objective: This study proposes a randomized, double-blind trial of adults patients presenting to the Emergency Department treated with Compazine for migraine, looking at the overall incidence of akathisia compared to control, as well as comparing IVP versus IV infusion.

Technical Approach: We propose the randomization of 150 consecutive adult patients who meet inclusion criteria over an estimated six to nine month period who present to the Emergency Department at Eisenhower Army Medical Center with chief complaint of headache, felt to be consistent with the diagnosis of migraine by the attending physician. Each patient will be randomized to one of three groups. 1) Compazine 10mg IVP followed by a placebo of 250cc of 5% dextrose and water (D5W) over 15 minutes. 2) D5W followed by Compazine 10mg in 250cc D5W over 15 min and 3) Toradol 30mg IV followed by an infusion of 250cc D5W IV over 15 minutes. The third will be considered the control group. All of the treatment arms are considered as standard therapies.

Progress: Study recently approved by IRC.

DETAIL SUMMARY SHEET

Date:	Protocol:	Status:
9 Sep 97	97-47	Ongoing

Title:	Emergency Medicine Trauma Lab

Start Date:	Est. Compl. Date:
Principal Investigator(s): Sean MCcloy, CPT, MC	**Facility:** Eisenhower Army Medical Center
Department/Service: Emergency Medicine	**Associate Investigators:** Richard Schwartz, MAJ MC Connie Laveri, CPT, MC Sal Wambsgans, MAJ, MC F. P. Craig Miner, MD Lisa Daylida, MD
Key Words: Training, animals, pain	
Accumulative MEDCASE Cost:	**Periodic Review Results:** Sep 97, Ongoing

Study Objective: Basic proficiency training of physicians working in the emergency department with necessary life-saving procedures. Refresher proficiency training of staff health care providers.

Technical Approach: One session will be held each month beginning at 0900 horus. One to two pigs will be used per session with 4-5 students and one instructror per pig. Participants will receive a one hour skills-review lecture. They will also receive an approximate 4 hour insturction period on emergency procedures with live, fully anesthetized animals. Under supervision, students will perform procedures such as venous cutdowns, intraosseous needle placements, diagnostic peritoneal lavage, transvenous pacemaker placements, pericardiocentesis, needle thoracostomy, tube thoracostomy, needle cricothyroidotomy, and surgical circothyroidotomy. Laboratory staff will assist in monitoring the animals during the lab. All animal manipulations will stop should a pig enter into a light plane of anesthesia during any portion of the lab and until anesthesia is reapplied by LASS personnel. All procedures will be performed using standard ATLS guidelines.

Progress: None. Study recently approved (September IRC meeting).

DETAIL SUMMARY SHEET

Date: 9 Sep 97	**Protocol:** 96-10	**Status:** Completed
Title:	Susceptibility to Varicella Infection and Cost-effectiveness of Varicella Vaccination	
Start Date: February 1996		**Est. Compl. Date:** August 1996
Principal Investigator(s): Joseph Degaetano, CPT, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Family Community Medicine		**Associate Investigators:** Anthony F. Jerant, CPT Ted D. Epperly, LTC, MC R. Daren Marionneaux, CPT, MC Andrew Hannapel, CPT, MC
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Completed

Study Objective: To determine the prevalence of susceptibility to varicella virus infection, as manifested by a lack of antibodies against the virus on serologic testing, in the improcessing Advanced Individual Training (AIT) student population at Fort Gordon.

Technical Approach: Two phases will be conducted: 1) a descriptive study which involves a questionnaire survey and a seroprevalence study for those soldiers giving voluntary informed consent. 2) a cost-effectiveness model utilizing data from the descriptive study, EAMC personnel, and the literature review.

Progress: Data collection (1,595 soldiers) now complete. Write-up in final stages of manuscript preparation for submission to journal. In process of mailing serology results to soldiers.

Problems Encountered: None.

DETAIL SUMMARY SHEET

Date: 9 Sep 97	Protocol: 97-27	Status: Ongoing
Title:	Association of Menstrual Irregularity and Skeletal Injury in Collegiate Athletes	
Start Date: May 1997		**Est. Compl. Date:** June 1998
Principal Investigator(s): Mark A. McGrail, CPT, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Family Community Medicine		**Associate Investigators:**
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Ongoing

Study Objective: This study is a self-report survey of female athletes in the sport of running, gymnastics, swimming, and volleyball that will attempt to define the relationship of skeletal injury and menstrual abnormalities within various groups of women. Variables to be assessed include medical and menstrual history, oral contraceptive and other medication use, athletic and training history, diagnosed injuries, as well as dietary habits.

Technical Approach: 300-500 subjects in each sport will be surveyed - ranging from ages 17-25. Each survey will be anonymous and will be numbered and tracked only so far as to which institution it was sent for administration to allow for determination of respons rate. Data will be analyzed using the appropriate descriptive statistics.

Progress: Surveys copied/returned from printer; in process of contacting college athletic directors to arrange for administration of surveys to athletes once they return for next semester.

Problems Encountered: None.

DETAIL SUMMARY SHEET

Date: 30 Sep 97	Protocol: 97-46	Status: Ongoing
Title:	The Prevalence of Sexual Concerns In a Population of Men, and What Barriers Exist for the Discussion of Sexual Concerns with Health Care Providers.	
Start Date: October 1997		**Est. Compl. Date:** March 1998
Principal Investigator(s): Jennifer T. Johnson, CPT, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Family Community Medicine		**Associate Investigators:** Margaret R.H. Nusbaum, DO Cathy Demastes, CPT, MC Rex Cabaltica, CPT, MC Anthony F. Jerant, MAJ, MC Andree Lloyd, PhD
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Ongoing

Study Objective: This study is designed to assess the prevalence of sexual concerns in a population of men who are eligible for military medical care. It is further designed to assess patient-perceived barriers to the discussion of sexual concerns during health care appointments.

Technical Approach: A sexual history will be taken since routine health maintenance exams involve examining the male genitalia. Information obtained from this study will provide physicians with an awareness of what changes need to be implemented in order to facilitate sexual health promotion. The sexual health care concerns of a sample of military medical beneficiaries will be assessed. The results will enhance the training of primary care providers to include sexual health care risk assessment.

Progress: None. Study recently initiated.

DETAIL SUMMARY SHEET

Date:	9 Sep 97	**Protocol**	95-28	**Status**	Ongoing
Title:	A Five Year Observational Study to Evaluate Clinical Response and Recurrence Rate in the Treatment of Basal Cell Carcinoma with Fluorouracil/Epinephrine Injectable Gel				

Date:	**Est. Compl. Date:**
Principal Investigator(s): James M. Baunchalk, LTC, MC	**Facility:** Eisenhower Army Medical Center
Department/Service: Medicine/Dermatology	**Associate Investigators:** John S. Pujals, CPT, MC
Key Words:	
Accumulative MEDCASE Cost:	**Periodic Review Results:** Sep 97, Ongoing

Study Objective: To describe the clinical response rate at three months post treatment, to describe the recurrence rate in patients with a clinical response at three months post treatment, and to confirm and evaluate the long-term safety and efficacy in patients with basal cell carcinoma.

Technical Approach: Each patient will have one lesion treated and evaluated. If more than one clinically diagnosed and/or biopsy proven eligible lesion is present, a randomization scheme for lesion selection will be used. Target enrollment for this institution is 10-15 patients aged 18 years or older. Study duration will be at least four months, with extended follow up for up to five years.

Subjects enrolled this reporting period: A total of 48 enrollees. Enrollment closed.

Progress: All patients have completed the 12-month follow-up phase of the study. There were four non-responders, 6 recurrences and 2 administrative drops 1 transfer, 1 expired). There are 36 patients remaining in the study.

Adverse Reactions Encountered: Three serious adverse events were reported this period. The first one involved a patient who reported at his 12-month visit in Nov 1966 that he had surgery at the VA in August for cancer of the tongue. He had reported various complaints of throat and ear pain since March 1996 and had visits to various clinics before being referred to the VA for surgery. The hospital summary revealed a diagnosis of squamous cell carcinoma of the tongue. A partial glossectomy, modified neck dissection and PEG were done on 15 August 1997. The patient was treated with the study drug in October 1995. The second patient was admitted to the hospital on 20 Jan 1997 for complaints of chest discomfort. A cardiac catheterization and angioplasty with stent placement were performed on 20 Jan 1997. The patient was discharged with a diagnosis of coronary artery disease with a non-Q wave myocardial infarction. The third SAE is a patient who had been hospitalized from 7 May to 9 May 1997 for an arrhythmia episode. Myocardial infarction and stroke were ruled out with a stress test. All three of the serious adverse events are considered unrelated to the study medications.

DETAIL SUMMARY SHEET

Date: 11Sep96	**Protocol:** 96-11	**Status:** Ongoing
Title:	A Double-Blind, Placebo Controlled Study to Evaluate the Fluorouracil/Epinephrine Injectable Gel (5FU/epi gel) as Compared to Placebo in the Treatment of Basal Cell Carcinoma, Matrix Pharmaceutical Protocol #62-94-3	
Start Date: Jan 96		**Est. Compl. Date:**
Principal Investigator(s): Mary Farley, MAJ, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Medicine/Dermatology		**Associate Investigators:** James Baunchalk, LTC, MC
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 96, Ongoing

Study Objective: To describe the histological and clinical response rate of 0.5 mL fluorouraci/epinephrine gel as compared to placebo when administered three times weekly for two weeks in patients with basal cell carcinoma and to evaluate the safety of the fluorouracil/epinephrine injectable gel when administered.

Technical Approach: Approximately 225 evaluable patients will have one lesion selected for study. Investigators will use a predetermined randomization schedule to select a target lesion in patients with more than one eligible lesion.

Number of subjects enrolled this report period: None

Progress: Study has not begun due to lack of drug. Drug should arrive within 2 weeks.

Problems Encountered: N/A

DETAIL SUMMARY SHEET

Date: 9 Sep 97	Protocol: 96-30	Status: Ongoing
Title:	Gastrointestinal Lesions in Iron Deficient Premenopausal Women. USAMRMC #4166023	
Start Date:		**Est. Compl. Date:**
Principal Investigator(s): Peter McNally, LTC, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Medicine\Gastroenterology		**Associate Investigators:** Matthew S.Z. Bachinski, MAJ, MC
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Ongoing

Study Objective: This study will be a prospective evaluation of premenopausal women who are found to have iron dieficiency anemia. Women who demonstrate iron deficiency anemia, by a ferritin less than 15mg/dl, and a hemoglobin less than 12Gm/l (World Health Organization criteria), will be eligible to participate.

Technical Approach: We propose to enroll approximately 100 premenopausal females age >18 years of age, who are military health care beneficiaries. Candidates will have demonstrated a clinically documented iron deficient anemia. The diagnosis of anemia will be based on priior laboratory evaluation with CBC, Fe studies including ferritin, and stool hemoccult status, by the primary physician.

Number of Subjects Enrolled During this Reporting Period: Twenty.

Progress: Although study is scheduled to end in December 1997, continuation has been requested since funding will support Research Coordinator another 6-8 months. Study continues.

Problems Encountered: None.

DETAIL SUMMARY SHEET

Date: 9 Sep 97	Protocol: 96-31	Status: Terminated
Title:	Clinical Evaluation of the LARA C^{13} Urea Breath Test for the Detection of H. Pylori	
Start Date: Sep 1996		**Est. Compl. Date:** Sep 1997
Principal Investigator(s): Peter McNally, LTC, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Medicine/Gastroenterology		**Associate Investigators:** Matthew S.Z. Bachinski, MAJ, MC
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97,Terminated

Study Objective: The primary objective is to evaluate the sensitivity and specificity of the LARA System in the detection of H. pylori infection. Results from the urea breath test will be primarily compared to the central histology results and to local bacterial culture results.

Technical Approach: Patients who are referred for upper GI endoscopy on clinical grounds and in whom biopsy is considered not to be contraindicated will be considered for entry into the study. Eligible patients who consent will be enrolled consecutively until there are approximately 200 to 300 patients per center. Subjects will be recruited by the investigator and/or his designated staff.

Number subjects enrolled: None.

Progress: None. Study approval was delayed due to sponsor closure at participating centers.

Problems Encountered: N/A

DETAIL SUMMARY SHEET

Date: 9 Sep 97	Protocol: 97-15	Status: Ongoing
Title:	Helicobacter Pylori Infection - A Chronic Antigenic Stimulus for Monoclonal Gammopathy of Unknown Significance (MGUS)	
Start Date: Jan 1997		**Est. Compl.** Dec 97
Principal Investigator(s): Stephen Sears, CPT, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Medicine/Gastroenterology		**Associate Investigators:** Peter McNally, LTC, MC Gunther Hsue, CPT, MC Frank Niagro, MAJ, MC Ramona Smith, LPN
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97,Ongoing

Study Objective: The identify a subset of MGUS patients who have H. pylori infection as the likely antigenic stimulus for their gammopathy by establishing an immunologic link between the two entities.

Technical Approach: A patient cohort from the Gastroenterology and Internal Medicine Clinics at DDEAMC who have both a diagnosis of MGUS and previous evidence of H. pylori infection will be utilized. A cohort of control patients from the Gastroenterology Clinic seen previously for abdominal complaints who have known prior H. pylori infection without MGUS willl also be identified, in addition ot a group with MGUS and no evidence of H. pylori infection. Each patient is to have blood results for SPEP, CBC, IFE, Quantitative Immunoglobulin and H. pylori Ab titers. Patients who meet the diagnostic criteria for both MGUS and prior H. pylori infection as well as all control patients will also have their serum further tested via Western Blot Immunoassay against an H. pylori antigen extract prepared in-house. Those patients who have a predominant clearly defined antigen-specific band of the same isotype as their monoclonal gamma globulin (previously determined by IFE), will be identified as having H. pylori infection as th antigen stimulus for thier MGUS. This is to be contrasted to the control group patients who should not demonstrate such a predominant isotype-specific band on their Western blots.

Number of patients enrolled: Thirteen.

Progress: These patients have completed the initial evaluation to include blood test, EGD and biopsy and follow up SPEP. Currently the comparison studies are being conducted between the two groups.

DETAIL SUMMARY SHEET

Date: 9 Sep 97	Protocol: 97-20	Status: Ongoing
Title:	Clinical Trial of a Piling Weck Guide Wire Bougie (Savory type) and Guide Wire	
Start Date: Mar 1997		**Est. Compl.** Feb 97
Principal Investigator(s): Peter McNally, LTC(P), MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Medicine/Gastroenterology		**Associate Investigators:** Matthew Bachinski, MAJ, MC Donald Lazas, MAJ, MC Stephen Sears CPT, MC
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97,Ongoing

Study Objective: To assess the Piling Weck silicone casing/PTFE under core guide wire bougie and guide wire as an acceptable or preferable alternative to the currently marketed product.

Technical Approach: Both the guide wire and bougie must be sterilized prior to use by autoclaving chemical soaking in Cidex or use of Steris System. The spring tip guide wire is negotiated through the stricture under fluoroscopy. The bougie dilater is slipped onto the guide wire and held with the right hand for sliding down the wire.

Number of patients enrolled: One.

Progress: Slow enrollment.

DETAIL SUMMARY SHEET

Date: 9 Sep 97	Protocol: 97-41	Status: Ongoing
Title:	A Multi-center,Randomized, Double-Blind, Eight Week Comparative Efficacy and Safety Study of H 199/18 20 mg, H 199/18 40 mg and Omerprazole 20 mg in Study Subjects With Erosive Esophagitis.	
Start Date: Sep 1997		**Est. Compl.**
Principal Investigator(s): Peter McNally, LTC(P), MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Medicine/Gastroenterology		**Associate Investigators:** Stephen R. Sears, CPT, MC Matthew Bachinski, MAJ, MC Leonard Little, LTC, MC
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97,Ongoing

Study Objective: The purpose of this study is to document the safety of H199/18 and to compare H199/18 20 mg qd, H199/18 40 mg qd and Omerprazole 20 mg qd with regard to complete healing of erosive esophagitis and improved GERD symptom resolution in subjects with erosive esophagitis.

Technical Approach: Patients will be accrued from 200 major medical centers in a consecutive fashion. All GERD patients undergoing EGD will be considered eligible for study. Ages are 18 to 75 yrs; male or non-lactating female. Females must be post menopausal or surgically sterilized or using acceptable form of birth control as determined by the investigator. Women of child-bearing have a negative pregnancy test at baseline.

Number of patients enrolled: 10

Progress: 13 patients screened; 10 patients enrolled, and 7 patients on study drug.

DETAIL SUMMARY SHEET

Date: 9 Sep 97	Protocol: 97-42	Status: Ongoing
Title:	A Multi-center,Randomized, Double-Blind, Six Month Maintenance Study to Compare the Efficacy, Safety, and Tolerability of H 199/18 20 mg, H 199/18 40 mg with Placebo in Healed Erosive Esophagitis Subjects.	
Start Date: Sep 1997		**Est. Compl.**
Principal Investigator(s): Peter McNally, LTC(P), MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Medicine/Gastroenterology		**Associate Investigators:** Stephen R. Sears, CPT, MC Matthew Bachinski, MAJ, MC Leonard Little, LTC, MC
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97,Ongoing

Study Objective: The purpose of this study is to document the safety of H199/18 and to compare H199/18 20 mg qd, H199/18 40 mg qd to placebo in the preventiono f symptomatic and endoscopic recurrence of esophagitis.

Technical Approach: Patients will be accrued from 75 major medical centers in a consecutive fashion. All GERD unergoing EGD will be considered eligible for study. Ages are 18 to 75 yrs; male or non-lactating female. Females must be post menopausal or surgically sterilized or using acceptable form of birth control as determined by the investigator. Women of child-bearing have a negative pregnancy test at baseline.

Number of patients enrolled: No patients enrolled due to the fact that this is a follow up study of protocol #97-41.

DETAIL SUMMARY SHEET

Date:	Protocol:	Status:
9 Sep 97	97-2	Ongoing

Title:	The Knowledge and Treatment of Essential Hypertension by Internal Medicine Residents Across Three Years of Training
Start Date: October 1996	**Est. Compl. Date:** February 1997
Principal Investigator(s): Mark Mataosky, MAJ, MC	**Facility:** Eisenhower Army Medical Center
Department/Service: Internal Medicine	**Associate Investigators:** David Bookstaver, Clinical Pharmacist Timothy Manown, CPT, MC Hernando Ramos, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	**Periodic Review Results:** Sep 97, Ongoing

Study Objective: To asses the knowledge base and therapeutic interventions planned by a group of internal lmedicine residents for the pharmacologic treatment of essential hypertension in a large, managed care, practice setting. A secondary objective is to assess the degree of agreement between staff, board certified internists and clinical pharmacists in the pharmacologic treatment of essential hypertension.

Technical Approach: This study will consist of three phases: 1) involves the administration of a comprehensive questionnaire on the knowlede of hypertension, the implications of treatment on mortality and morbidity, and the pharmacologic choices available for treatment. This will be given the first month of the academic year to all residents in all three years of traiing. 2) involves the collection of data on the actual treatment of hypertension by internal medicine residents, and 3) involves the comparison of the opinions of staff internists as compared to clinical pharmacists as to the appropriateness of what the hous officers wished to do with regard to the patients blood pressure medication.

Progress: All data is collected and is now in the synthesizing process. Study should be completed in next 2 to 3 weeks.

Problems Encountered: None.

DETAIL SUMMARY SHEET

Date: 9 Sep 97	Protocol: 96-28	Status: Ongoing
Title:	A Double-Blind, Randomized, Placebo Controlled Study to Evaluate the Renal Protective Effects of Losartan in Patients with Non-Insulin Dependent Diabetes Mellitus and Nephropathy, Merck & Co., Inc Protocol 147-00	
Start Date:		**Est. Compl. Date:**
Principal Investigator(s): Lloyd D. Hancock, MAJ, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Medicine/Nephrology		**Associate Investigators:** Gregory A. Pisel, MAJ, MC Carl A. Gibson, MAJ, MC
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Ongoing

Study Objective: To demonstrate that losartan compared to placebo will reduce the number of NIDDM patients with nephropathy who experience doubling of serum creatinine, ESRD or death.

Technical Approach: The primary hypothesis is that long term treatment with losartan compared to placebo in patients with noninsulin dependent diabetes mellitus and nephropathy will increase the time to first event and decrease the incidence of doubling of serum creatinine, end stage renal disease or death. A secondary hypothesis is that losartin will increase the time to first event and decrease the incidence of cardiovascular morbidity/mortality compared to placebo. Of tertiary interest is the effect of losartan compared to placebo on quality of life and healthcare resource utilization.

Number of patients enrolled this period: Three.

Progress: All patients are doing well.

Problems Encountered: Due to stringent entry criteria, it has been difficulty getting enough patients enrolled in the study. Eight to ten patients are desired per site. One serious adverse event for EAMC. Patient admitted to CCU, EAMC to rule out MI. Patient continues on protocol with no change to study meds.

DETAIL SUMMARY SHEET

Date:	9 Sep 97	**Protocol**	94-95	**Status**	Ongoing
Title:	The Effect of r-HuEPO in Patients with Small Cell Lung (SCLC): A Randomized, Double-Blind Placebo-Controlled Trial, N93-004				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Kenneth I. Fink, LTC, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology			**Associate Investigators:** Robert A. Avery, MAJ, MC Raj R. Gupta, M.D. Robert D.Vallion, LTC, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 97, Ongoing		

Study Objective: To determine the effect of r-HuEPO vs placebo on tumor response in small cell lung cancer (SCLC) patients receiving therapy with VP-16 and cisplatin. The secondary objective of this study is to determine the effect of r-HuEPO on erythroid parameters in SCLC patients by measuring hemoglobin levels and transfusion requirements.

Technical Approach:

Number of subjects enrolled this reporting period: 2

Progress: A total of 5 patients are enrolled.

Problems encountered: Not enough patients seen at EAMC who meet the protocol criteria.

DETAIL SUMMARY SHEET

Date:	9 Sep 97	**Protocol**	95-1	**Status**	Ongoing
Title:	A Natural History Study of Patients with Low Grade Lymphoid Malignancies Treated with Fludarabine				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Kenneth I. Fink, LTC, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology			**Associate Investigators:** Raj R. Gupta, M.D. Robert D. Vallion, LTC, MC Robert A. Avery, MAJ, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 97, Ongoing		

Study Objective: To perform a natural history study of patients with low-grade lymphoid malignancies treated with fludarabine. This study will also determine the degree and duration of immunodysfunction in patients with low-grade lymphoid maligancies treated with fludarabine.

Technical Approach: A data collecting schedule is outlined in appendix I of the protocol. Immunophenotyping (lymphocyte panel analysis) will be performed by flow cytometry employing a standard whole blood lysis procedure as described by the manufacturer of the lysis reagents.

Number of subjects enrolled this reporting period: None

Progress: None. Study continues.

Problems encountered: There have been no eligible patients to participate in this study.

DETAIL SUMMARY SHEET

Date:	9 Sep 97	**Protocol:**	95-26	**Status**	Closed
Title:	A Double-Blind, Randomized, Phase 3, Multicenter Study of Suramin and Hydrocortisone versus Hydrocortisone and Placebo in the Treatment of Patients with Metastatic,Hormone-Refractory Prostate Carcinoma (Stage D2) (Protocol 1003-01)				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Kenneth I. Fink, LTC, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology			**Associate Investigators:** Stephen G. Oswald, COL, MC Robert D. Vallion, LTC, MC Robert A. Avery, MAJ, MC Raj R. Gupta, M.D.		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 97, Closed		

Study Objective: To determine suramin's effect on pain, performance status, prostate specific antigen (PSA), measurable and osseous disease, quality of life, and survival in patients with hormone-refractory prostate carcinoma, and to evaluate the safety of suramin.

Technical Approach: Eligible patients will undergo a 2-week baseline period in which narcotic pain medications are stabilized. At the end of the baseline period, patients will be stratified prospectively on the basis of PSA level and presence of measurable disease and randomly assigned to the suramin or placebo treatment group.

Progress: None. Study closed

Problems Encountered: None.

DETAIL SUMMARY SHEET

Date:	9 Sep 97	**Protocol**	95-32	**Status**	Ongoing
Title:	A Randomized, Double-Blind, Placebo Controlled Study to Evaluate the Effect of Cisplatin/Epinephrine Injectable Gel (Product MPI 5010) When Administered Intratumorally for Achievement of Treatment Goals in Recurrent or Refractory Squamous Cell Carcinoma of the Head and Neck.				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Kenneth I. Fink, LTC, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology			**Associate Investigators:** Raj R. Gupta, M.D. Robert D. Vallion, LTC, MC Robert A. Avery, MAJ, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 97, Ongoing		

Study Objective: To assess achievement of an identified improvable primary treatment goal selected for the most troublesome tumor in patients with recurrent or refractory squamous cell carcinoma of the head and neck.

Technical Approach: Randomized, double-blind, placebo controlled study of approximately 90 evaluable patients. Patients are stratified by total baseline tumor volume. Patients within each stratum are assigned in a 2:1 ratio to receive treatment with cisplatin/epinephrine gel (MPI 5010) or placebo gel in accordance with a predetermined randomization schedule.

Number of subjects enrolled: None.

Progress: None. Study reapproved for 1 yr.

Problems encountered: Protocol has difficult inclusion criteria.

DETAIL SUMMARY SHEET

Date:	9 Sep 97	**Protocol**	95-33	**Status**	Ongoing
Title:	A Study to Evaluate the Effect of Cisplatin/Epinephrine Injectable Gel (Product MPI 5010) When Administered Intratumorally for Achievement of Treatment Goals in Accessible Tumors of any Histology. Matrix Protocol MP #403-93-2.				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Kenneth I. Fink, LTC, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology			**Associate Investigators:** Raj R. Gupta, M.D. Robert D. Vallion, LTC, MC Robert A. Avery, MAJ, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 97, Ongoing		

Study Objective: To assess achievement of an identified improvable primary treatment goal selected for the most troublesome tumor following up to 6 weekly treatments of MPI 5010 administered intratumorally in patients with accessible tumors of various histologies.

Technical Approach: Open-label study of approximately 60-65 evaluable patients.

Number of subjects enrolled this reporting period: None.

Progress: Three patients have been screened.

Problems encountered: This protocol has difficult inclusion criteria and there has not been a large number of qualified patients who are willing to participate.

DETAIL SUMMARY SHEET

Date: 9 Sep 97	Protocol: 96-16	Status: Terminated
Title:	Comparison of TLC D-99 Doxorubicin Liposome Injection Versus Doxorubicin Injection in Metastatic Breast Cancer	
Start Date:		**Est. Compl. Date:**
Principal Investigator(s): Kenneth I. Fink, LTC, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Medicine/Oncology		**Associate Investigators:** Raj R. Gupta, M.D. Yeini G. Thompson, Ph.D
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 1997, Terminated

Study Objective: To compare the safety and efficacy of treatment with TLC D-99 liposomal doxorubicin with free (standard) doxorubicin in patients with metastatic breast cancer; to compare the cardiac safety of TLC D-99 with free doxorubicin using left ventricular ejection measurements; to compare the pharmacokinetic characteristics of TLC D-99 with free doxorubicin at selected sites.

Technical Approach: TLC D-99 and free doxorubicin will be administered by intravenous infusion over 1 hour every three weeks Treatment will be administered on an outpatient basis except for patients participating in the extended pharmacokinetic monitoring . Vital signs including temperature, blood pressure and respiratory rate will be obtained at each treatment cycle prior to drug administration. The starting dose of TLC D-99 will be 75mg/m^2 given at a constant rate by intravenous infusion over 1 hour. The starting dose of free doxorubicin will also be 75 mg/m^2 given by intravenous infusion over 1 hour.

Number of Subjects Enrolled this Reporting Period: None

Progress: None, study terminated due to no enrollment.

DETAIL SUMMARY SHEET

Date: 9 Sep 97	Protocol: 96-29	Status: Ongoing
Title:	A Double-Blind, Placebo-Controlled, Randomized Multicenter Study to Evaluate the Efficacy and Safety of Long-Term Treatment with 20mg or 50mg Ibandronate Administered Daily Orally for at Least 60 Weeks in Patients with Metastatic Bone Diseases due to Breast Cancer, Boehringer Mannheim Corporation, Therapeutics Division, Study Number MF4434, IND#50,378	
Start Date:		**Est. Compl. Date:**
Principal Investigator(s): Kenneth I. Fink, LTC, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Medicine/Oncology		**Associate Investigators:** Robert A Avery, MAJ, MC Raj R. Gupta, M.D. Robert D. Vallion, LTC, MC
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Ongoing

Study Objective: To demonstrate the efficacy of 20mg and 50mg ibandronate versus placebo administered orally daily for at least 60 weeks on the reduction of the incidence of bone complications of metastatic disease.

Technical Approach: This study is based on a double-blind, placebo-controlled, parallel-group, randomized design. Patients will be randomized to one of three groups at visit 2. Depending on randomization, the patients will be treated daily either with placebo or 20mg or 50mg ibandronate orally. According to randomization, patients receive 20mg, or 50mg ibandronate daily for at least 60 weeks. The maximum treatment period will be 96 weeks. No formalized stopping rules are defined. There will be no interim analysis of efficacy. The patients will be selected by means of the inclusion and exclusion criteia at visit 1.

Number of subjects enrolled this reporting period: None.

Progress: Three patients enrolled. One patient chose to withdraw. The study is expected to be completed nationally by Dec 1997 when the total number of subjects are accrued. Presently, the study remains open.

Problems Encountered: None.

DETAIL SUMMARY SHEET

Date: 20 Aug 97	Protocol: 96-34	Status: Terminated
Title:	A Randomized Phase III Trial of Carboplatin and Paclitaxel +/- Ethyol (Amifostine) in Patients with Non-Small Cell Lung Cancer, US Bioscience, Protocol WR-56	
Start Date: 12 Sep 96		**Est. Compl. Date:**
Principal Investigator(s): MAJ Robert A. Avery, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Medicine/Oncology		**Associate Investigators:** LTC Kenneth I. Fink, MC COL Robert Vallion, MC Raj R. Gupta, M.D.
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Terminated

Study Objective: The objective of this study is to determine if Ethyol can reduce the incidence of myelotoxic-associated events without interfering with the antitumor efficacy of the regimen. This will be a multi-center, randomized, open-label, controlled, parallel groups trial.

Technical Approach: Eligible patients will be randomized to receive carboplatinpaclitaxel or carboplatin/paclitaxel plus Ethyol. Randomization will be 1:1 between the two treatment arms. Patients will remain on study until they have completed six cycles of chemotherapy or until fulfillment of any of the criteria for removal from study as set forth in the protocol.

Progress: None. Study terminated by sponsor due to low accrual.

Number of Patients: Two.

DETAIL SUMMARY SHEET

Date:	Protocol:	Status:
8 Oct 97	97-28	Ongoing
Title:	Efficacy and Tolerability of Oral Itasetrom 1mg BID and 2.5mg BID Compared with Oral Ondansetron 8mg BID over Three Consecutive Days in the Prohylatic Treatment of Vomiting and Nausea in Patients Undergoing Moderately Emetogenic Chemotherapy. A Randomized, Double-Blind, Multicenter, Parallel-Group Comparison with Amendment #2.	
Start Date: June 1997		**Est. Compl. Date:**
Principal Investigator(s): Kenneth I. Fink, LTC, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Medicine/Oncology		**Associate Investigators:** Robert A. Avery, MAJ, MC Robert D. Vallion, LTC, MC Raj R. Gupta, MD
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Ongoing

Study Objective: To assess the efficacy, safety, and tolerability of oral itasetron hydrochloride compared with an active comparator in the prevention of chemotherapy-induced emesis 24 hours after initiation of chemotherapy and during the entire observation period.

Technical Approach: Efficacy will be measured by the frequency of complete responders within the first 24 hours after initiation of chemotherapy. In addition the complete response will be measured during the entire three-day treatment period. Patients will be monitored during the trial for changes in physical examination, vital signs, ECG, and laboratory results. A total of 723 patients will be enrolled nationwide, 15 at DDEAMC, 18 yrs and older.

No Patients Enrolled This Reporting Period: Three.

Problems Encountered: None

DETAIL SUMMARY SHEET

Date: 8 Oct 97	Protocol: 97-43	Status: Ongoing
Title:	Efficacy and Tolerabilityof 2.5mg Itasetron Intravenously and of 32mg Ondansetron Intravenously in the Prevention of Vomiting and Nausea in Patients Undergoing CisPlatin (>75mg/m2) Containing Chemotherapy.	
Start Date: October 1997		**Est. Compl. Date:**
Principal Investigator(s): Kenneth I. Fink, LTC, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Medicine/Oncology		**Associate Investigators:** Robert A. Avery, MAJ, MC Robert D. Vallion, LTC, MC Raj R. Gupta, MD
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Ongoing

Study Objective: To evaluate the efficacy, safety, and tolerability of one-time IV administration of 2.5mg Itasetron Hydrochloride and 32mg of IV Ondansetron standard therapy in the prevention of vomiting and nausea in patients undergoing high-dose cisplatin containing chemotherapy.

Technical Approach: The trial will be performed as a randomized, double-blind, actively controlled, multicenter, parallel-group comparison. The overall trial schedule is depicted below. Before inclusion potentially eligible patients will be screened during day -10 to 1 before or on treatment day 1. Eligible patients will then be randomly assigned to one of the two treatments: 2.5mg Itasetron or 32mg Ondansetron diluted in 50ml of 0.9% saline administered once before the start of chemotherapy. Blindnessof the treatment will be secured by using ampules which are identical in shape, size, weight and color.

Progress: Study recently implemented. No patients enrolled.

DETAIL SUMMARY SHEET

Date: 9 Oct 97	Protocol: 96-2	Status: Terminated
Title:	Double-Blind, Placebo-Controlled, Efficacy and Safety Study of TLC C-53 in Patients with Acute Respiratory Distress Syndrome	
Start Date:		**Est. Compl. Date:**
Principal Investigator(s): Warren L. Whitlock, LTC, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Medicine/Pulmonary		**Associate Investigators:** Wayne T. Honeycutt, LTC, MC William T. Brown, MAJ, MC Jorge Thompson, PA
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Oct 97, Terminated

Study Objective: To demonstrate that the time to off-ventilator (i.e., mechanical ventilator turned off due to clinical improvement and patient no longer requires mechanical ventilator support) for TLC C-53 treated patients is significantly less than for placebo-treated patients.

Technical Approach: This is a Phase III, double-blind, placebo-controlled, randomized, parallel, multicenter study in hospitalized patients with a clinical diagnosis of ARDS. A sufficient number of investigative sites will be recruited to allow enrollment of approximately 340 patients to achieve at least 284 evaluable patients. Each investigative site should enroll at least six to eight patients. Patients who meet all the inclusion/exclusion criteria wil be randomized in a 1:1 ratio to receive either TLC C-53 or placebo (D_5W) intravenously every 6 hours via a 1-hour infusion over 7 days for a total of 28 doses.

Number of Subjects Enrolled: 1

Progress: One patient enrolled this reporting period. Sponsor terminated enrollment 6 May 1997. Our site was officially closed on 16 July 1997.

Problems Encountered: Difficulty finding patients to enroll.

DETAIL SUMMARY SHEET

Date: 9 Sep 97	Protocol: 96-3	Status: Ongoing
Title:	Randomized Placebo Controlled Trial of MAK 195F in Sepsis with Hyperinflammatory Response.	
Start Date: Nov 1995		**Est. Compl. Date:**
Principal Investigator(s): Warren L. Whitlock, LTC, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Medicine/Pulmonary		**Associate Investigators:** Wayne T. Honeycutt, LTC, MC William T. Browne, LTC, MC Lawrence S. Lepler, MAJ, MC Jorge Thompson, PA
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Ongoing

Study Objective: To assess the efficacy of MAK 195F in patients suffering from sepsis presenting with elevated interleukin-6 (IL-6 levels ("sepsis with hyperinflammatory response") indicated by a positive rapid test provided for the study (designed to indicate IL-6 levels $\geq$ 1,000 pg/ml) in terms of decreased 28-day all-cause mortality. A decrease of 8% will be considered clinically relevant.

Technical Approach: Patients with diagnosed sepsis according to the entry criteria will be tested once with a rapid test for IL-6. The patient will be randomized, stratified by rapid IL-6 test kit results, to receive MAK 195F or placebo and will be followed for survival for 28 days. The study will continue until 500 patients with rapid IL-6 tests are randomized. These patients will be equally distributed to the MAK 195F-treated and the placebo group.

Number of Subjects enrolled this period: 0

Progress: Total of three patients enrolled. Enrollment process continues.

Problems Encountered: None.

DETAIL SUMMARY SHEET

Date:	Protocol:	Status:
9 Sep 97	97-8	Closed
Title:	Prospective, Randomized, Double-Blind Comparison of the Safety and Efficacy of Bay 12-8039 400mg QD x 10 days vs 400mg QD x 5 days vs. Clarithromycin 500 mg BID x 10 days for the Treatment of Patients with Acute Exacerbations of Chronic Bronchitis.	
Start Date: Dec 1996		**Est. Compl. Date:**
Principal Investigator(s): Warren L. Whitlock, LTC, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Medicine/Pulmonary		**Associate Investigators:** Wayne T. Honeycutt, LTC, MC James W. Thompson, MD Lawrence S. Lepler, MAJ, MC Jorge Thompson, PA
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Closed

Study Objective: To compare the safety and efficacy of BAY 12-8039 400mg PO QD for 5 days vs BAY 12-8039 400 mg QD x 10 days vs. Clarithromycin 500 mg BID x 10 days for the treatment of patients with acute exacerbations of chronic bronchitis.

Technical Approach: Each study site will be given a packet of information which details for both the patient and thesite/study coordinator how the outcome data will be collected by Bayer's outside consultant, Reilly Associates. Patients will be telephoned at four separate time points at a place and time convenient to their individual request. An outcome assessment notification form is included within each outcome information packet. Subjects will be instructed that they will be telephoned at a time and place of their choice, and this information will be captured on the outcomes assessment notification form and faxed to the outside consultant.

Progress: Nine patients have been enrolled - two with early termination. A total of 35 have been screened.

Problems Encountered: One patient was dropped because of COPD exacerbation.

DETAIL SUMMARY SHEET

Date:	Protocol:	Status:
9 Sep 97	97-9	Ongoing
Title:	The Effect of Nasal Positive Pressure Ventilation on Exercise Performance in Chronic Obstructive Pulmonary Disease	
Start Date: Dec 1996		**Est. Compl. Date:**
Principal Investigator(s): Melanie Guerrero,CPT, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Medicine/Pulmonary		**Associate Investigators:** Warren L. Whitlock, LTC, MC James W. Thompson, MD Jody Jean Paul, RRT Jorge Thompson, PA
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Ongoing

Study Objective: To identify the physiologic changes,if any, following the use of CPAP in patients with severe COPD and to show a difference in exercise performance and gas exchange following treatment with non-invasive nocturnal ventilation.

Technical Approach: Subjects will include two groups of patients. One group will be patients with known severe COPD without chronic respiratory failure. The second group will be patients with known severe COPD and chronic respiratory failure manifested by resting $PaCO2 > 45$ mmHg. Patients will be disqualified if they suffer an exacerbation of COPD during the study period.

Progress: Presently, no patients are enrolled. Study remains ongoing.

DETAIL SUMMARY SHEET

Date: 9 Sep 97	**Protocol:** 97-10	**Status:** Complete
Title:	Prospective, Uncontrolled, Non-Blind, Multicenter Clinical Trial of the Safety and Efficacy of BAY 12-8039 400mg PO QD for 10 Days in the Treatment of Patients With Commuity Acquired Pneumonia.	
Start Date: Dec 1996		**Est. Compl.** March 1998
Principal Investigator(s): Warren L. Whitlock, LTC, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Medicine/Pulmonary		**Associate Investigators:** Wayne T. Honeycutt, LTC, MC James W. Thompson, MD Lawrence S. Lepler, MAJ, MC Jorge Thompson, PA
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Complete

Study Objective: To compare the safety and efficacy of BAY 12-8039 400mg PO QD for 5 days vs BAY 12-8039 400 mg QD x 10 days for the Treatment of Community Acquired Pneumonia.

Technical Approach: Approximately 250 patients will participate in this study with 10 being from Eisenhower Army Medical Center. Each patient will receive BAY 12-8039 400 mg (1 tablet) by mouth once a day for 10 days. The total length of time you are being asked to participate in this study will range from 5 to 6 weeks.

Progress: Ten patients enrolled. All SAE's reported.

Problems Encountered: One medication error occurred. This incident was properly reported. Protocol is complete.

DETAIL SUMMARY SHEET

Date: 9 Sep 97	Protocol: 97-11	Status: Closed
Title:	Microchemistry Analyzers in the Intensive Care Unit, Do They Make A Difference?	
Start Date: Dec 1996		**Est. Compl.** March 1998
Principal Investigator(s): Daniel F. Lee, DO, CPT, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Medicine		**Associate Investigators:** William T. Brown, ,MAJ, MC James W. Thompson, MD Lawrence S. Lepler, MAJ, MC Jorge Thompson, PA
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Closed

Study Objective: To qualify the amount of blood drawn from ICU patients both when a bedside microchemistry analyzer is available and when it is not. To measure the amount of blood discarded due to "line clearing" during both periods. To correlate the difference in amount of blood drawn during both periods to definitive clinical parameters such as hematocrit and number of transfusions.

Technical Approach: This is a two-stage study, each stage lasting four weeks. The first four weeks, all patients newly admitted to the ICU will be enrolled in the study. Collected data will include APACHE II score, the number of phlebotomies per day, daily hematocrit, total volume of blood discarded per day in cc's, total volume of blood for conventional laboratory testing per day in cc's, whether an arterial, central, or pulmonary artery catheter is in place, site of the phlebotomy, peripheral venipuncture, arterial, central, or pulmonary artery, and number of blood transfusions the patient received. The second four weeks all newly admitted patients to the ICU wil be enrolled in the study. This time a microchemistry analyzer will be used and the volume of blood will be documented. The data will be evaluated. Hematocrit and transfusion requirements will be assessed to determine if the use of the microchemistry analyzer reduced the need for transfusions.

Progress: Project completed; study closed.

DETAIL SUMMARY SHEET

Date:	Protocol:	Status:
9 Sep 97	97-21	Ongoing
Title:	A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study of Pulmicort (budesonide) Turbuhaler, 400ug Administered Once Daily for 12 Weeks in Adult Patients with Inhaled Steroid-Dependent Asthma.	
Start Date: Apr 1997		**Est. Compl.**
Principal Investigator(s): Warren L. Whitlock, LTC, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Medicine/Pulmonary		**Associate Investigators:** Wayne T. Honeycutt, LTC, MC James W. Thompson, MD Jorge Thompson, PA
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Ongoing

Study Objective: To compare the safety and efficacy of once daily administration of Pulmicort Turbuhaler, versus placebo, in adult patients aged 18 years or greater with inhaled steroid-dependent asthma.

Technical Approach: Participants in this study will be assigned by random chance to receive either budesonide or placebo. The primary care physician will be notified of the patient's participation in the study. Approximately 180 patients, distributed among approximately 20 study centers in the USA, will enter this study.

Progress: Eleven patients have been enrolled. Two were dropped due to asthma exacerbations.

Problems Encountered: None. Study remains open.

DETAIL SUMMARY SHEET

Date: 9 Sep 97	Protocol: 97-22	Status: Ongoing
Title:	A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study of Pulmicort (budesonide) Turbuhaler, 400ug Administered Once Daily for 12 Weeks in Adult Patients with Non-Steroid Dependent Asthma	
Start Date: Apr 1997		**Est. Compl.**
Principal Investigator(s): Warren L. Whitlock, LTC, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Medicine/Pulmonary		**Associate Investigators:** Wayne T. Honeycutt, LTC, MC James W. Thompson, MD Jorge Thompson, PA
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Ongoing

Study Objective: To compare the safety and efficacy of once daily administration of Pulmicort Turbuhaler, versus placebo, in adult patients aged 18 years or greater with nonsteroid dependent asthma.

Technical Approach: Participants in this study will be assigned by random chance to receive either budesonide or placebo. The primary care physician will be notified of the patient's participation in the study. Approximately 180 patients, distributed among approximately 20 study centers in the USA, will enter this study.

Progress: Five patients have been enrolled.

Problems Encountered: None. Study remains open.

DETAIL SUMMARY SHEET

Date: 9 Sep 97	Protocol: 97-26	Status: Ongoing
Title:	A Randomized, Multicenter, Third Party Blinded Trial Comparing Trovafloxacin with Amoxicillin/Clavulanate (Augmentin) with or without Erythromycin for the treatment of Community Acquired Pneumonia.	
Start Date: May 1997		**Est. Compl.**
Principal Investigator(s): Warren L. Whitlock, LTC, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Medicine/Pulmonary		**Associate Investigators:** Wayne T. Honeycutt, LTC, MC James W. Thompson, MD Jorge Thompson, PA
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Ongoing

Study Objective: To test the hypothesis that Trovafloxacin as empiric monotherapy has similar efficacy to amoxicillin/clavulanate with or without erythromycin for the treatment of community acquired pneumonia appropriate for oral treatment. A secondary objective is to compare the safety and toleration of the two regimens.

Technical Approach: This study will be conducted in approximately 30 centers within the United States. Aproximately 320 subjects aged 18 years and older who have been diagnosed with Community Acquired Pneumonia and qualify for the study will be enrolled. Participants will undergo tests including a chest x-ray that will confirm that they have Community Acquired Pneumonia and their physician has determined that they qualify for this study. Patients must not have taken any antibiotics for at least 24 hours or longer within 3 days of this visit. They must not have any type of allergy or sensitivity to any other type of antibiotic. The participation will last approximately 28 to 35 days.

Progress: Four active patients are enrolled.

Problems Encountered: None. Study remains open.

DETAIL SUMMARY SHEET

Date: 9 Sep 97	**Protocol:** 97-29	**Status:** Ongoing
Title:	A Comparison of Salmeterol versus Theophylline versus Salmeterol Plus Theophylline in COPD Patients.	
Start Date: June 1997		**Est. Compl.**
Principal Investigator(s): Warren L. Whitlock, LTC, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Medicine/Pulmonary		**Associate Investigators:** Wayne T. Honeycutt, LTC, MC James W. Thompson, MD Jorge Thompson, PA
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Ongoing

Study Objective: To compare the safety and efficacy of Salmeterol xinafoate 42mcg (2 puffs) BID to Theophylline (Slo-Bid sustained released, 100mg capsules BID) at therapeutic levels (10-15mcg/ml) to Salmeterol xinafoate 42mcg (2 puffs) BID plus Theophylline (Slo-Bid sustained released, 100mg capsules BID) at therapeutic levels (10-15mcg/ml) in COPD patients. Also, to compare the effectiveness of these treatments for improving patient-perceived COPD-related deficits in quality of life (as measured by the Chronic Respiratory Disease Questionnaire (CRDQ) scores) and to assess patient-rated satisfaction with study drug.

Technical Approach: This study will be conducted in approximately 30 centers within the United States. Aproximately 320 subjects aged 18 years and older who have been diagnosed with Community Acquired Pneumonia and qualify for the study will be enrolled. Participants will undergo tests including a chest x-ray that will confirm that they have Community Acquired Pneumonia and their physician has determined that they qualify for this study. Patients must not have taken any antibiotics for at least 24 hours or longer within 3 days of tis visit. They must not have any type of allergy or sensitivity to any other type of antibiotic. The participation will last approximately 28 to 35 days.

Progress: A total of six patients have enrolled. Two active patients, two early termination due to COPD exacerbation, and two with screen failures.

Problems Encountered: None.

DETAIL SUMMARY SHEET

Date:	Protocol:	Status:
9 Sep 97	97-32	Ongoing
Title:	Continuous Infusion vs Intermittent Bolus Furosemide in the Treatment of Oliguric Acute RenalFailure. A Randomized, Placebo Controlled Trial.	
Start Date: June 1997		**Est. Compl.**
Principal Investigator(s): David Bookstaver, Pharm D		**Facility:** Eisenhower Army Medical Center
Department/Service: Medicine/Pulmonary		**Associate Investigators:** David Jones, DO James W. Thompson, MD Jorge Thompson, PA William Brown, MD
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Ongoing

Study Objective: This study is designed to replicate the standard approach to acute renal failure in the intensive care unit.

Technical Approach: 240 patients will be enrolled in this study. Patients over the age of 18 without regard to gender will be eligible for enrollment. Any patients who have developed acute oliguric renal failure will be studied.

Progress: None. Study recently implemented.

DETAIL SUMMARY SHEET

Date: 20 Aug 97	**Protocol:** 95-20	**Status:** Completed
Title:	Impact of Telemedicine/Telenursing on Patients & Costs	
Start Date:		**Est. Compl. Date:**
Principal Investigator(s): Loretta Schlachta, LTC, AN		**Facility:** Eisenhower Army Medical Cener
Department/Service: Nursing		**Associate Investigators:** Lisa Bush, RN, MSN Richard McKnight, MAJ, MC Thomas E. Knuth, MAJ, MC Betsey S. Blakeslee, PH.D Placidia Clark, 1LT, AN Noel Poindexter, 1LT, AN Jack Horner, DAC Thomas Baker, 2LT Arlene Lowenstein, Ph.D Maribeth Johnson, Consultant
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Completed

Study Objective: To identify the impact of home based telenursing on patients' health outcomes and hospital utilization costs.

Technical Approach: The study is designed to answer the question "will telenursing effect healthcare utiliiilization?" To answer the question, the latest low band width telemedicine technology in the form of desktop computers with a motion camera and appropriate medical instrumentation will be placed in sample patients' homes, and patients will be "visited" electronically by a telenurse.

Progress: The data collection period for this study concluded on 28 Feb 97. The study clearly showed that health care costs could be reduced by the placement of telemedicine technology in patient homes, particularly for patients who are frequent users of the emergency facilities due to chronic conditions. A second phase of this study is planned and funded to further build on the experiences of the present phase. Newer, more cost effective technology will be employed.

Number of Subjects Enrolled to Date: None. Study completed.

DETAIL SUMMARY SHEET

Date:	Protocol:	Status:
9 August 97	95-21	Closed

Title: Efficacy of Clinical Case Management in the Military	
Start Date:	**Est. Compl. Date:**
Principal Investigator(s): Diane L .Brown, LTC, AN	**Facility:** Eisenhower Army Medical Center
Department/Service: Nursing	**Associate Investigators:** Diane S. Brown, MSN Gloria L. Whitehurst, MSN
Key Words:	
Accumulative MEDCASE Cost:	**Periodic Review Results:** Sep 97, Closed

Study Objective: To determine and compare the effects of managed care at a US Army Medical Center and an Army Community Hospital.

Technical Approach: Care will be directed by a nurse clinical case manager who manages the patient through both inpatient and outpatient setting, coordinating resources as appropriate.

Progress: Repeated measures of patient satisfaction, neuro physician communication and staff satisfaction completed. 100% turn over of assigned care managers Jun-Sep 95. Now have 3 ANC case managers. Began case management in Psychiatry June 95.

Number of Subjects Enrolled to Date: N/A

Problems Encountered: None. Study closed.

DETAIL SUMMARY SHEET

Date: 9 Aug 97	**Protocol:** 95-42	**Status:** Ongoing
Title:	Risk ReductionStrategies for Pre-Menopausal Military African-American (25-45) Women With CHD or Associated Risk Factors	
Start Date:		**Est. Compl. Date:**
Principal Investigator(s): Joyce Newman Giger, CPT, MS		**Facility:** Eisenhower Army Medical Center
Department/Service: Nursing		**Associate Investigators:** Herman Taylor, M.D. Ora Strickland, Ph.D. Mary Anderson Hardy, Ph.D.
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Ongoing

Study Objective: To further specify the risk factors for CHD in African-American women; to determine if there are particular genetic phenotypes which include lipoprotein (a), apolipoprotein E, endothelia-1, tumor necrosis factor alpha and mutations within the beta subunit of the epithelial sodium channel which are genetic predictors of CHD, hypertension and overt diabetes in premenopausal African American women; and test the impact of a comprehensive risk reduction program designed to reduce risk factors for the worsening of CHD in premenopausal African American women.

Technical Approach: A two-phase study will be conducted. Phase I will include recruiting a sample of 150 pre-menopausal (25-45 years of age) African American women who have CHD or a high risk for CHD and compare them with a sample of 150 African American premenopausal women who are low risk for CHD in order to further specify risk factors of CHD in premenopausal women. Phase II will include a minimum of 200 eligible women with CHD or risk factors for CHD being randomly assigned to either a culturally appropriate comprehensive risk reduction program or a control group to determine its impact on risk factors for CHD in this population.

Progress: Data collection completed. Data analysis being conducted at University of Alabama under the direction of Dr. Giger.

Number of Subjects Enrolled to Date: 110.

DETAIL SUMMARY SHEET

Date: 9 Sep 97	Protocol: 97-7	Status: Completed
Title:	Anxiety and Hypertension in Middle-Aged Black and White Men	
Start Date: November 1996		**Est. Compl. Date:**
Principal Investigator(s): Elaine Neary, MSN		**Facility:** Eisenhower Army Medical Center
Department/Service: Nursing		**Associate Investigators:**
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Completed

Study Objective: To determine if middle-aged hypertensive black men experience more anxiety than middle-aged hypertensive white men. Findings should provide valuable information to nursing regarding the amount of anxiety experienced by black men versus white men. They will also allow nurses to explore cultural considerations in utilizing therapeutic strategies to decrease anxiety and hypertension in patients.

Technical Approach: A research questionnaire packet will be utilized. Screening room clinic nursing personel will be informed that research is being conducted on black and white hypertensive middle-aged men. If the patient agrees to volunteer, the staff member will enter the client's height, weight, pulse, and blood pressure from the patient's chart on the top sheet of the packet. Completed questionnaires will be returned to a box on the reception counter. If the participant would like to know the results of this study he will be asked to provide hi name and address on a separate sheet of paper and the results will be mailed to him. Another questionnaire (demographic sheet) will provide information of age, gender, race, taking blood pressure medication, current medl problems, marital and educational status, family income and if the client smokes or consumes alcoholic beverages. Ages will be between 45-59 years.

Progress: Received a very minimal number of surveys (22) needed 126.

Problems Encountered: Minimal returns. No significant results. Study completed.

DETAIL SUMMARY SHEET

Date:	Protocol:	Status:
9 Sep 97	92-43	Terminated

Title: The First Break Psychosis Study	
Start Date: Sep 92	**Est. Compl. Date:** May 95
Principal Investigator(s): Elaine Correnti, LTC, MC	**Facility:** Eisenhower Army Medical Center
Department/Service: Psychiatry & Neurology	**Associate Investigators:** Richard Borison, MD Manuel Casanova, MD Laura Davidson, PhD Bruce Diamond, MD Sahebarao P. Mohadik, MD Sukdeb Mukherjee, MD Thomas Ralston, LTC, MC Russell Scheffer, CPT, MC Neal Trent, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	**Periodic Review Results:** Sep 97, Terminated

Study Objective: To determine whether specific biological abnormalities previously found in chronic schizophrenic patients are present at the beginning of the illness and, if so, to examine their relations to clinical characteristics of the illness; and to examine whether selected clinical, historical, and biological measures are predictive of short-term clinical outcome in patients experiencing their first episode of psychosis.

Technical Approach: Patients will undergo comprehensive psychiatric, neuropsychological, and neurological examinations at baseline, and blood samples will be taken for determination of RBC activities of specific enzymes and measurement of tritiated imipramine binding in platelets. A skin biopsy will be performed to develop fibroblast cell lines in culture and examine whether fibroblasts from patients show the abnormalities of growth and morphology noted in studies of chronic schizophrenic patients.

Subjects enrolled to date: 44

Progress: Forty-four patients experiencing the first episode of psychosis were enrolled in the study protocol.

Problems Encountered: None.

DETAIL SUMMARY SHEET

Date: 9 Sep 97	Protocol: 95-8	Status: Terminated
Title:	Attitudes, Experiences and Coping Strategies in Career Army Soldiers	
Start Date:		**Est. Compl. Date:**
Principal Investigator(s): Elaine E. Correnti, LTC, MC, DPN		**Facility:** Eisenhower Army Medical Center
Department/Service: Psychiatry		**Associate Investigators:** Mary Cruser, CPT, MC
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Terminated

Study Objective: To examine personality and environmental factors that enhance the well-being of women with ten years of experience in the military.

Technical Approach: A total of 400 subjects will be sampled. Half of the sample will be male and half will be female. The sample will consist of equal numbers of officers and enlisted soldiers. Subjects will be asked to complete a demographic and general information questionnaire.

Number of Subjects Enrolled to Date: 400

Progress: Datea collection completed. Two presentations at the American Psychiatric Association Annual Meeting - May 1997. Two presentations at the Army Behavioral Sciences Conference - 1997. Study terminated.

DETAIL SUMMARY SHEET

Date: 9 Sep 97	**Protocol:** 95-30	**Status:** Ongoing
Title:	The Efficacy of Sertraline in Chronic Pain Management	
Start Date:		**Est. Compl. Date:**
Principal Investigator(s): Scott McCall, CPT, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Psychiatry		**Associate Investigators:** Rance W. Humphreys, CPT, MC Darcelle M.Delrie, LTC, MC
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Ongoing

Study Objective: To evaluate the efficacy of Sertraline in the treatment of patients with a variety of chronic pain syndromes..

Technical Approach: Participants will be randomized to Sertraline or placebo for six weeks. Patients will come in for visits in weeks 1,4,7, and 10 of the study. Visits will last up to 30 minutes during which time the patient will be given the next week's amount of medication, and be asked questions concerning their thoughts, feelings and pain symptoms, as well as possible side effects they may be experiencing from the medication.

Number of Subjects Enrolled to Date: 12

Progress: Approximately twenty patients screened, twelve enrolled and nine completed study.

Problems Encountered: Enrollment slow due to inadequate advertising.

DETAIL SUMMARY SHEET

Date: 9 Sep 97	Protocol: 96-13	Status: Terminated
Title:	A Study of the Effect of Antidepressant Treatment on Smoking Cessation Rates in Depressed Smoking Cessation Candidates	
Start Date:		**Est. Compl. Date:**
Principal Investigator(s): Scott McCall, CPT, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Psychiatry		**Associate Investigators:** Celso G. Bolet, COL, MC Dan Laeupple, CPT, MC Stephen Bowles, CPT, MC Drew Steiner, MAJ, MC
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Terminated

Study Objective: To determine if improved success in smoking cessation will occur in nicotine-addicted individuals, after implementation of antidepressant treatment.

Technical Approach: Each study subject will be assigned a three digit code number. The list of coded patients' identities will be maintained in secure files at all times. Data will be collected using the following variables: age, smoking history and patterns, knowledge and attitudes about smoking, health history, familial and personal psychiatric history.

Number of patients enrolled during this period: None.

Progress: None. Study terminated.

DETAIL SUMMARY SHEET

Date:	Protocol:	Status:
9 Sep 97	96-18	Ongoing

Title: Comparison of the Conners' Continuous Performance Test and Gordon Diagnostic System as Tools to Assist in the Diagnosis and Treatment of Children and Adolescents with Attention Deficit Hyperactivity Disorder

Start Date:	**Est. Compl. Date:**
Principal Investigator(s): William S. Evans, Jr, LTC, MC	**Facility:** Eisenhower Army Medical Center
Department/Service: Psychiatry	**Associate Investigators:** Daphne Albright, PhD
Key Words:	
Accumulative MEDCASE Cost:	**Periodic Review Results:** Sep 97, Ongoing

Study Objective: This study will investigate two measures used to evaluate attention, vigilance, impulsivity, and distractibility in children and adolescents. The Continuous Performance Test (CPT) which is widely used in both clinical and research settings as a standardized , computer administered test of attention. The Gordon Diagnostic System (GDS) is an automated test which has separate subtests designed to assess vigilance, distractibility, and impulsivity, and has been widely used in both research and practice since its development.

Technical Approach: Patients will be asked to complete the long form of the CBCL, the child or adolescent's classroom teacher(s) will be asked to complete both the TRF and the CTRS-39 to provide additional information about each subject's behavior. Each subject will be randomly assigned to one of two conditions which will determine whether he/she is tested with the CPT or the GDS first. All subjects will be administered the full CPT and the Delay and Vigilance subtests of GDS. Statistical analysis will compare parental reports, teacher reports, and the child or adolescent's performance on the CPT and GDS.

Total number of patients enrolled: 44

Progress: Fifteen additional patients have been enrolled.

Problems Encountered: Many cases have been closed or families have Pcs'd. It has been difficult to get families to return to the clinic once thechild has been stabilized on meds.

DETAIL SUMMARY SHEET

Date: 9 Sep 97	Protocol: 97-14	Status: Ongoing
Title:	A Comparative Study Examining Intensive Outpatient Weight Treatment to a Historical Control Group.	
Start Date: January 1997		**Est. Compl. Date:** December 2000
Principal Investigator(s): Stephen V. Bowles, MAJ, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Psychiatry		**Associate Investigators:** Kelli Metzger, R.D. Carla Long, PhD
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Ongoing

Study Objective: To identify the variables within this model of behavioral change (focusing on eating, exercise, and attitude) that increase the likelihood of improved health for participants in this program. The variables examined will be in the areas of: quality of life, mental fitness, physical fitness, and lab tests.

Technical Approach: There will be individual, gender, and cultural differences on the medical lab results, weight loss, PT scores, and psychological test results suggesting improved health for the experimental group. There will also be a difference in the weight loss and PT scores of the experimental and control group. Groups will consist of 10-20 subjects ranging from 18 yrs and older - males and females. All must be currently active duty.

Total number of patients enrolled: 40

Progress: At six months participants have maintained 12.8 lb wieght loss.

Problems Encountered: None.

DETAIL SUMMARY SHEET

Date: 9 Sep 97	Protocol: 97-24	Status: Ongoing
Title:	Neuropsychological and Motoric Features of Drug-Naive Patients	
Start Date: April 1997		**Est. Compl. Date:** March 2000
Principal Investigator(s): Elizabeth E. Correnti, LTC, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Psychiatry		**Associate Investigators:** Lloyd S. Miller, M.D. Gary D. Southwell, MAJ, MC Nancy A. Harpold, CPT, MC Thomas L. Gillespie, CPT, MC
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Ongoing

Study Objective: To compare newly diagnosed psychiatric hospital patients and past psychiatric patients on measures of cognition and force-steadiness.

Technical Approach: The aims of this study will be achieved by utilizing a single experimental subject group consisting of newly admitted, drug-naive patients admitted to the DDEAMC, Fort Gordon, GA. The data will be compared to a SCID-diagnosed, schizophrenia patient population data base already collected, and to a normal control group, also previously collected. Subjects will be tested on a broad series of neuropsychological tasks identified to assess multiple cognitive domains with pariticular emphasis on the areas of attention, memory, problem solving, and motoric functioning areas previously identified as often impaired in persons with schizophrenia.

Total number of patients enrolled: 1

Progress: Equipment has been transferred from the University of Georgia. A psychology techician has been trained to conduct the study testing.

Problems Encountered: None.

DETAIL SUMMARY SHEET

Date: 9 Sep 97	Protocol: 90-36	Status: Ongoing
Title:	Treatment of Internal Contamination by Plutonium and Other Transuranic Elements with Two Investigational New Drugs (Ca-DTPA and Zn-DTPA)	
Start Date:		**Est. Compl. Date:**
Principal Investigator(s): Robert J. Kaminski, LTC, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Radiology/Nuclear Medicine		**Associate Investigators:**
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Ongoing

Study Objective: The principal objective of this protocol is to obtain approval from the IRC to use Ca-DTPA and Zn-DTPA for the treatment of patients at Eisenhower Army Medical Center who are internally contaminated with plutonium or other transuranic elements.

Progress: This is not an investigational study. Protocol has enabled EAMC to obtain Ca-DTPA and Zn-DTPA from the Oak Ridge Institute for Science and Education for the emergency treatment of individuals who are internally contaminated with plutonium or other transuranic elements. No patients were treated this reporting period.

DETAIL SUMMARY SHEET

Date:	Protocol:	Status:
9 Sep 97	94-80	Terminated
Title:	The Use of Vitamin A in the Reversal of Corticosteroid Induced Defects in Wound Healing (Rattus Norvegius)	
Start Date:		**Est. Compl. Date:**
Principal Investigator(s): Scott R. Duffin, LTC, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Surgery/Orthopedics		**Associate Investigators:** K. Jeffrey, MD, MCG
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Terminated

Study Objective: To address the effectiveness of Vitamin A in reversing the detrimental effects of steroids on wound and tissue healing. The dose and duration at which Vitamin A accomplishes will also be evaluated.

Technical Approach:

Progress: None. Study terminated.

Number of subjects enrolled: None.

DETAIL SUMMARY SHEET

Date: 9 Sep 97	Protocol: 94-90	Status: Closed
Title:	The Epidemiology of Youth Soccer Injuries	
Start Date:		**Est. Compl. Date:**
Principal Investigator(s): John Kragh, MAJ, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Surgery/Orthopedics		**Associate Investigators:** Dean Taylor, MAJ, MC
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Closed

Study Objective: To understand youth soccer injuries.

Technical Approach: The study design will be a prospective case control at one location over several years. There will be no medication utilized for this study. The type population served will be the participants in the Augusta ARsenal Spring Shootout (AASS). the number of subjects will be approximately 7,500 (1,500x 5 years) with an age range between 6-19 yrs., both male and female. Inclusion criteria for this study will be AASS participants injured in participation; exclusion criteria will be those not injured in participation.

Progress: None. Study closed.

Number of subjects enrolled: 1500.

DETAIL SUMMARY SHEET

Date:	Protocol:	Status:
9 Sep 97	94-91	Closed
Title:	Comparison of Rotational Stability of Oblique Fibula Fractures Fixed with Bioabsorbable Screws Compared to Stainless Steel Screws in the Human Malleolus	
Start Date:		**Est. Compl. Date:**
Principal Investigator(s): Joseph J. Legan, MAJ, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Surgery/Orthopedics		**Associate Investigators:** David Browm, CPT, MC Joseph Erpelding, LTC, MC Dennis Runyan, COL, DE
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Closed

Study Objective: To compare the rotational stability of distal afibula fixed with 4.5 MM PGA polyglycolic acid screws (bioscience Ltd, Tampere, Finland) versus 3.5mm (Synthes, USA) stainless steel cortical screws in cortical bone.

Technical Approach: This will be an in-vitro study utilizing matched cadaver fibulas. Results will be recorded in Newtons-meters. This manner to test rotational stability of fixed fractures has been previously substantiated..

Progress: None. Study closed.

DETAIL SUMMARY SHEET

Date: 9 Sep 97	Protocol: 94-97	Status: Closed
Title:	Basic General/Vascular Surgical Technique Training Laboratoary Using a Porcine Model	
Start Date:		
Principal Investigator(s): MAJ (P) James H. North, Jr., MC	**Facility:** Eisenhower Army Medical Center	
Department/Service: Surgery	**Associate Investigators:** LTC David Rivera, MC	
Key Words:		
Accumulative MEDCASE Cost:	**Periodic Review Results:** Sep 97, Closed	

Objective: Basic proficiency training of surgical interns, surgical residents, and other select surgical ancillary personnel approved by the principal instructor(s) in general soft tissue and vascular surgical techniques (both laparotomy and laparoscopic procedures). Advanced/refresher proficiency training of staff surgeons in new state-of-the-art or seldom used soft tissue and vascular surgical techniques.

Technical Approach: The training laboratory shall be conducted twice monthly (normally the 2nd & 4th Thursday of each month). Each laboratory session shall be scheduled for 1200 - 1500 hours on the appointed day. One pig shall be used for each laboratory session. At least one instructor shall be present and conduct each training session. Not more than 4 students will be trained during a given laboratory.

Number of subjects enrolled for reporting period: N/A

Progress: None. Study closed. New literature presently being done - new study will be submitted for approval.

DETAIL SUMMARY SHEET

Date: 9 Sep 97	**Protocol:** 95-13	**Status:** Ongoing
Title:	Utilization of Goats (Capra hircus) For Advanced Trauma Life Support (ATLS) Training of DOD Medical Department Personnel	
Start Date:		
Principal Investigator(s): MAJ(P) James H. North, Jr., MC	**Facility:** Eisenhower Army Medical Center	
Department/Service: Surgery	**Associate Investigators:** LTC David Rivera, MC MAJ John Hamelink , MC CPT Kim Vlach, MS, DVM	
Key Words:		
Accumulative MEDCASE Cost:	**Periodic Review Results:** Sep 97, Ongoing	

Objective: Frequently, physicians are called upon to administer life-saving care to trauma patients. In many cases, these physicians are not familiar with these life-saving procedures, e.g., insertion of a chest tube, cricothyroidotomy, pericardiocentesis, diagnostic peritoneal lavage, or venous cutdown. The objective of this training is to teach physicians five safe, life-saving methods.

Technical Approach: The ATLS training course offers the opportunity in the treatment of blunt and penetrating trauma in sufficient amount to train 48 physicians, dentists, nurses, physician assistants, and other health care professionals. This course is dedicated to the first hour of initial assessment and transport of trauma patients. For this reason, live animal models are used in the ATLS program as a teaching method for hands-on instruction in surgical techniques and trauma resuscitation.

Number of subjects enrolled for reporting period: N/A

Progress: None. New literature is presently being done - new study will be submitted for approval.

DETAIL SUMMARY SHEET

Date: 9 Sep 97	**Protocol**	95-31	**Status:** Closed
Title:	Does Arginine Promote Wound Healing In Chronic Foot Ulcers?		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Anthony B. Cresci, MAJ, DPM		**Facility:** Eisenhower Army Medical Center	
Department/Service: Surgery/Orthopedics		**Associate Investigators:** Gail Cresci, T.D., C.N.S.D. Robert Martindale, M.D., Ph.D.	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Closed	

Study Objective: To determine the effects of supplemental oral intake of the non-essential amino acid arginine on wound healing.

Technical Approach: Patients with chronic foot ulcers will be randomized utilizing the last digit of their social security number to receive either oral dietary supplement of 30 grams arginine per day or a placebo.

Number of subjects enrolled this reporting period: 0

Progress: None. Study closed.

DETAIL SUMMARY SHEET

Date: 20 Aug 97	**Protocol**	95-34	**Status:** Ongoing
Title:	Comparative Study of the Clinical Efficacy of two Dosing Regimens of Eulexin		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Douglas Soderdahl, MAJ, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Surgery/Urology		**Associate Investigators:**	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Ongoing	

Study Objective: To compare the clinical effectiveness of a new dosing regimen for administering flutamide to the currently indicated dosing regimen.

Technical Approach: This is a Phase IV, multicenter trial in which 400 evaluable patients with de novo Stage M, metastatic prostate cancer will be randomized to a group. Patients will enter the study no later than two weeks after the screening visit and will be randomly assigned to a treatment group at Time 0. Flutamide therapy will be initiated the same day as either surgical or medical castration, and continued for three months.

Number of subjects enrolled this reporting period: 1

Progress: A total of 5 patients have been entered and completed to date. A new amendment was submitted to allow for more patients to be enrolled. Study ongoing.

Problems encountered: Slow enrollment.

DETAIL SUMMARY SHEET

Date:	Protocol:	Status:
20 Aug 97	96-6	Terminated
Title:	The Cross Table Lateral Radiograph in the Estimation of Bone Loss in the Pelvic Acetabulum	
Start Date: December 1995		**Est. Compl. Date:**
Principal Investigator(s): MAJ Wallace B. Brucker, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Surgery (General)		**Associate Investigators:**
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Terminated

Study Objective: To examine the use of the cross table lateral in the measurement of acetabular bone loss.

Technical Approach: A cadaver pelvis with attached femora will be cleaned of all possible non-hip joint soft tissue. Radiographs will be taken 30 degrees from a horizontal line between the acetabuli with the beam directed cephalad through the contralateral hip. These positions will simulate inter-technician positioning error and demonstrate the validity of this technique despite a wide range of "cross table laterals. An "intact", no bony defects, acetabulum will be studied as a control.

Number of subjects enrolled this period: 0

Progress: None. Study terminated.

Problems Encountered: Difficulty with the reproducibility of positioning for films.

DETAIL SUMMARY SHEET

Date:	Protocol:	Status:
20 Sep 97	96-7	Ongoing
Title:	Anterior Transposition vs. Decompression of the Ulnar Nerve for Cubital Tunnel Syndrome: A Prospective Randomized Study.	
Start Date:		**Est. Compl. Date:**
Principal Investigator(s): MAJ Micahel G. Raab. :TC		**Facility:** Eisenhower Army Medical Center
Department/Service: Surgery (Orthopedic)		**Associate Investigators:** Joseph Legan, CPT, MC Jane Sadler, CPT, MC David Koon, CPT, MC
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Ongoing

Study Objective: To compare the efficacy of the anterior subcutaneous transposition versus simple decompression of the ulnar nerve for patients with cubital tunnel syndrome who fail conservative therapy.

Technical Approach: Subjects will be patients with cubital tunnel syndrome undergoing surgical treatment by the principal investigator. Patients eligible for study will be limited to those with simple cubital tunnel syndrome. They will be graded as having mild, moderate or severe disease.

Number patients enrolled this period: 10

Progress: Ten patients enrolled. Study continues.

DETAIL SUMMARY SHEET

Date: 20 Sep 97	Protocol 96-8	Status: Ongoing
Title:	The Hand Diagram in Carpal Tunnel Syndrome	
Start Date:		**Est. Compl. Date:**
Principal Investigator(s): MAJ Michael G. Raab, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Surgery (Orthopedic)		**Associate Investigators:** CPT David Brown, MC MAJ Wallace B. Brucker, MC
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Ongoing

Study Objective: To determine the predictive value of the hand diagram (HD) in carpal tunnel syndrome (CTS).

Technical Approach: All patients seen in the DDEAMC Orthopaedic Clinic by the principal investigator for CTS will fill out a hand diagram. This diagram will show areas of pain, numbness, and paresthesia about the hand and wrist. A certain number of these patients will undergo carpal tunnel releases (CTR). Those patients selected for operative CTR will undergo preoperative testing.

Number of patients enrolled this period: 0

Progress: Twenty patients enrolled. Study continues.

DETAIL SUMMARY SHEET

Date:	Protocol	Status:
20 Sep 97	96-9	Terminated
Title:	Molecular Studies of Breast Cancer in Three Ethnic Groups	
Start Date:		**Est. Compl. Date:**
Principal Investigator(s): William Calton, MAJ, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Surgery (Orthopedic)		**Associate Investigators:**
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Terminated

Study Objective: To determine the types and frequency of somatic and/or germline mutations in p53 associated with the breast cancer of three ethnic groups of women.

Technical Approach: Collect paraffin embedded and/or frozen archival breast tumor tissues and obtain a thorough history of the patient from tumor registry. If patient is alive, gather information concerning family background, lifestyle, and food habits. Obtain fresh tumor tissue and normal tissue samples from women undergoing surgery fro the removal of breast tumors and store the samples in liquid nitrogen or in the freezer. Blood will also be collected from the patient in the presence of EDTA.

Progress: None. Insufficient number of patients enrolled. Study terminated.

DETAIL SUMMARY SHEET

Date: 9 Sep 97	Protocol 96-14	Status: Terminated
Title:	Bone Marrow Aspirate Injection for Scaphoid Non-Unions	
Start Date:		**Est. Compl. Date:**
Principal Investigator(s): CPT Kevin O'Shea, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Surgery (Orthopedic)		**Associate Investigators:** MAJ Michael Travis, MC
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Terminated

Study Objective: To evaluate the efficacy of injection of bone marrow aspirate into the fracture site of chronic scaphoid fractures in a prospective, randomized fashion. This study is being done in conjunction with Walter Reed Army Medical Center where the study is already underway.

Technical Approach: The plan is to examine the efficacy of bone marrow aspirate injection into the wrist of patients with a chronic fracture of the carpal scaphoid. Patients will be identified from the general orthopedic clinic population at each facility. A consent form will be signed by each patient volunteering for the study. They will be randomized by using the serial envelope method which will be strictly maintained by the primary investigator and the local coordinator of each site.

Number of patients enrolled: 2

Progress: None. Study terminated.

DETAIL SUMMARY SHEET

Date: 9 Sep 97	Protocol: 96-32	Status: Ongoing
Title:	Testing of the Superficial Radial Sensory Nerve and its Relationship to Pain Relief with Carpal Tunnel Release in Diabetics:	
Start Date:		**Est. Compl. Date:**
Principal Investigator(s): CPT Kevin O'Shea, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Surgery (Orthopedics)		**Associate Investigators:** Michael G. Raab, MAJ,MC
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Ongoing

Study Objective: To prospectively evaluate the relationship between conduction velocity abnormalities in the ipsilateral superficial radial nerve and the outcome of carpal tunnel release in diabetic patients with the clinical diagnosis of carpal tunnel syndrome.

Technical Approach: All diabetic patients with the clinical diagnosis of carpal tunnel syndrome will be invited to participate in this study. These patients will complete the Brigham and Women's Hospital carpal tunnel questionnaire and the AAOS General Health Survey including information on duration and severity of their diabetes. The surgery will then be performed and the surveys will be repeated. All collected data will then be collated and an attempt will be made to correlate the inverse relationship between superficial radial nerve involvement and postoperative pain relief with carpal tunnel syndrome.

Number of patients enrolled: 1

Progress: None. Principal investigator is TDY for six months - will review study upon return.

DETAIL SUMMARY SHEET

Date: 9 Sep 97	Protocol: 96-35	Status: Ongoing
Title:	A Multicenter,Randomized, Parallel, Double-Blind, Dose Ranging Study of Subcutaneous SR 90107A/ORG 31540 with an Assessor-Blind, Comparative Control Group of LMWH in the Prevention of Deep Vein Thrombosis After Elective Total Hip Replacement, DRI 2643	
Start Date:		**Est. Compl. Date:**
Principal Investigator(s): MAJ Scott R. Duffin, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Surgery (Orthopedics)		**Associate Investigators** LTC Curtis J. Alitz, MC MAJ Michael G. Raab, MC MAJ Timothy R. Stapleton,MC CPT Kevin J. O'Shea, MC
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Ongoing

Study Objective: The primary objectives of this study are to determine the optimum dose of a once-daily subcutaneous injection of SR 90107A/ORG 31540 starting postoperatively and continuing for a minimum of five days for DVT (deep venous thrombosis).

Technical Approach: One hundred and forty subjects will be enrolled and complete the study in each of the five SR90107A/Org 31540 dose groups and 210 subjects will be enrolled and complete the study in the LMWH group. In order to assure that 910 subjects complete the study, a maximun of 1170 subjects will be enrolled. At the time of randomization and again just prior to the first dose of study medication, the investigator will reconfirm that the subject meets all inclusion/exclusion criteria.

Subjects enrolled: 16

Progress: Slowly obtaining patients nationwide. Study will remain open to increase enrollment.

DETAIL SUMMARY SHEET

Date: 9 Sep 97	Protocol: 97-16	Status: Completed
Title:	Prevention of Adhesions to Polypropylene Mesh in Abdominal Wall Repairs, Using Bioresorbable Hyaluronic Acid Membrane in a Rabbit Model.	
Start Date:		**Est. Compl. Date:**
Principal Investigator(s): Robert C. Dinsmore, CPT, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Surgery		**Associate Investigators** William C. Calton, MAJ, MC
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Completed

Study Objective: To determine if the use of Hyaluronic Acid in the form of a bioresorbable membrane will effectively prevent visceral adhesions to Polypropylene mesh.

Technical Approach: New Zealand White Rabbits will be randomized to one of two treatment limbs Animals will be euthanized at 30 days post-op at which time tissues will be collected and studied for adhesions and mesh incorporation. All animals will be subjected to a ventral midline abdominal incision. The abdominal wall will be resected in the midline. This defect will be closed with polypropylene mesh and 2-0 vicryl suture on a taper needle. In the experimental limb (limb 1) 12 animals will have HA membrane placed posterior to the mesh. In the control limb (limb 2) 12 animals will have polypropylene mesh placed without HA membrane.

Subjects enrolled: 16

Progress: Investigation completed successfully. Paper submitted for publication.

DETAIL SUMMARY SHEET

Date: 9 Sep 97	Protocol: 97-17	Status: Ongoing
Title:	Amendment to "Regulation of Bacterial Growth in an Open Fracture".	
Start Date:		**Est. Compl. Date:**
Principal Investigator(s): Kevin O'Shea, CPT, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Surgery		**Associate Investigators** Thomas Buxton, PhD
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Ongoing

Study Objective: This study examines the effect of various compounds in the establishment of osteomyelitis. The hypothesis is: L-fucose and arachidonic acid will qualitatively and quantitatively affect the establishmentof acute osteomyelitis.

Technical Approach: Albino Sprague-Dawley rats will be used. The rats will be housed, fed a standard rodent diet, and provied water. We will use strain SMH of Staphylococcus aureus. S. aureus cells will be cultured with shaking of 18 hours in 150 ml of broth and incubated for 3 hours to obtain log-phase growth. The organism will be centrifuged and the pellet washed nd reconstituted in isotonic saline to a concentration of 3×10^6/ 5ul. The bacterial density will be estimated spectrophotometrically.

Subjects enrolled: None.

Progress: Data collection complete. Analysis in progress.

DETAIL SUMMARY SHEET

Date:	Protocol:	Status:
9 Sep 97	97-19	Ongoing

Title:	Effect of Fibrin Glue on Lymph Drainage after Surgery for Human Breast Cancer: A Prospective Randomized Trial
Start Date:	**Est. Compl. Date:**
Principal Investigator(s): James A. Harris, MAJ, MC	**Facility:** Eisenhower Army Medical Center
Department/Service: Surgery	**Associate Investigators** David E. Rivera, COL, MC Larry T. Bourke, COL, MC
Key Words:	
Accumulative MEDCASE Cost:	**Periodic Review Results:** Sep 97, Ongoing

Study Objective: To determine the efficacy of fibrin glue to decrease lymph drainage after modified radical mastectomy (MRM) and axillary lymphadenectomy (AL) alone in the treatment of human breast cancer.

Technical Approach: Women of any age undergoing AL or MRM for stage I to IIIa breast cancer will be recruited. Patients with direct invasion of the chest wall, inflammatory breast cancer, ulceration of the skin or preoperative chest or axilary radiation will be excluded. The hypothesis to be tested is that fibrin glue, applied to the MRM and AL wound cavity, encourages flap adherence, seals open lymphatic channels and decreases lymph drainage after surgical treatment of human breast cancer. Patients will be randomized to the study group or the control group at the time of the preoperative visit. This study will compare the control group to the study group for two separate procedures: modified radical mastectomy and axillary lymphadenectomy alone. The goal is to randomize a total of 120 patients; approximately 60 patients with MRM and 60 with AL..

Progress: Protocol has begun and several patients (6-8) enrolled.

Problems encountered: Two patients developed post operative wound infections. Fibrin glue probably did not play a role in the infection.

DETAIL SUMMARY SHEET

Date: 9 Sep 97	Protocol: 97-25	Status: Ongoing
Title:	External Fixation Commonly Used in Distal Radius Fractures vs Internal (Becton) Plating: A Biomechanical Study	
Start Date:		**Est. Compl. Date:**
Principal Investigator(s): Timothy D. Rankin, CPT, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Surgery		**Associate Investigators** Michael G. Raab, MAJ, MC
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Ongoing

Study Objective: To evaluate the mechanical strength of the internal plate in comparison to standard external fixators used in distal radius fractures.

Technical Approach: The concept involves placement of the device (Becton plate) below the skin between the extensor tendons and teh periosteum with solid fixation to the bone thus providing the benefits of distraction and fixation without the disadvantages of the external fixator's infections, etc. Removal of the device can be done without a second trip to the Emergency Room. .

Progress: Data completely collected; manuscript currently in progress.

Problems Encountered: Difficulty holding the aluminum tubes in the instrument. Blocks were designed to fit each end and drilled to hold the aluminum tubes.

DETAIL SUMMARY SHEET

Date: 9 Sep 97	Protocol: 97-30	Status: Ongoing
Title:	A Multicenter Concurrent Control Randomized Open-Label Assessor-Blind Dose-Ranging Study of Org 31540/SR 90107A in the Prophylaxis of Deep Vein Thrombosis in Subjects Undergoing Total Knee Replacement Surgery	
Start Date:		**Est. Compl. Date:**
Principal Investigator(s): Arlon H . Jahnke, MAJ, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Surgery		**Associate Investigators** Scott R. Duffin, LTC, MC Michael G. Raab, MAJ, MC David E. Koon, CPT, MC Yeini G. Thompson, PhD
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Ongoing

Study Objective: To establish the appropriate dose of Org 31540/SR90107A for a Phase III study for the prophylaxis of DVT following total knee replacement surgery.

Technical Approach: Subjects will receive one of five different dos regimens of Org 31540/WR90107A: 0.75, 1.5, 3.0, 6.0 and 8.0 mg sc, o.d. If a dose group is dropped after the interim analysis, subjects will be randomized to one of the remaining dose groups. Approx. 25 subjects will be randomized at approx. 18 to 25 centers. The screening period is within 1 to 2 weeks prior to the start of surgery.

Subjects enrolled: None.

Progress: None. Study continues.

DETAIL SUMMARY SHEET

Date: 9 Sep 97	Protocol: 97-35	Status: Ongoing
Title:	Cholecystectomy vs. Observation for Biliary Dyskinesia: Results of a Multicenter Prospective Randomized Trial	
Start Date:		**Est. Compl. Date:**
Principal Investigator(s): Michael W. Blaney, CPT,MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Surgery		**Associate Investigators** James A. Harris, MAJ, MC
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Ongoing

Study Objective: To better define the natural history and the optimal treatment of biliary dyskinesia by comparing immediate cholecystectomy with observation..

Technical Approach: All patients referred who undergo a CCK-HIDA scan because of biliary colic like symptoms without gallstones on ultrasound are included in this study. At the time of initial evaluation, patients who meet the criteria will undergo an initial history and symptom questionnaire, and an upper GI endoscopy in order to rule out other causes of the patient's symptoms.

Subjects enrolled: 0

Progress: Study continues.

DETAIL SUMMARY SHEET

Date: 9 Sep 97	Protocol: 97-44	Status: Ongoing
Title:	Use of Nifedipine in the Treatment of Anal Fissure	
Start Date:		**Est. Compl. Date:**
Principal Investigator(s): James H. North, LTC,MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Surgery		**Associate Investigators** James Frizzi, CPT, MC David E. Rivera, COL., MC
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Ongoing

Study Objective: To investigate in a prospective randomized trial the effect of the use of oral nifedipine in the nonoperative management of chronic fissure in ano when compared with standard nonoperative therapy.

Technical Approach: The study is designed to investigate the hypothesis that the oral use of nifedipine in conjunction with standard nonoperative therapy will improve the healing rate for patients with chronic fissure in ano and decrease the need for surgical therapy.

Subjects enrolled: 0

Progress: Study continues.

DETAIL SUMMARY SHEET

Date: 9 Sep 97	**Protocol** 91-35	**Status:** Ongoing
Title:	SWOG 8947 Central lymphoma serum repository protocol. (Companion study to SWOG 8516, 8736, 8809 or 8816)	
Start Date:	**Est. Compl. Date:**	
Principal Investigator(s): Kenneth I. Fink, LTC, MC	**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Oncology/Pathology	**Associate Investigators:** Robert D. Vallion, LTC, MC Robert A. Avery, MAJ, MC Raj Gupta, MD Randy L. Hammill, LTC, MC	
Key Words:		
Accumulative MEDCASE Cost:	**Periodic Review Results:** Sep 97, Ongoing	

Study Objective: To establish a central lymphoma serum repository that will serve as a resource to provide specimens for current and future scientific studies. To utilize the SWOG database to perform clinicopathologic correlations with the results of those studies.

Technical Approach: Blood sample will be drawn and shipped to the Serum Repository Laboratory for testing.

Number of subjects enrolled for reporting period: None.

Progress: Two patients enrolled with no problems encountered this period.

DETAIL SUMMARY SHEET

Date: 9 Sep 97	**Protocol** 91-41	**Status:** Ongoing	
Title:	SWOG 8736 Treatment of localized non-Hodgkin's lymphoma: Comparison of Chemotherapy (CHOP) to Chemotherapy plus Radiation Therapy		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Kenneth I. Fink, LTC, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Oncology/Pathology		**Associate Investigators:** Robert D. Vallion, LTC, MC Robert A. Avery, MAJ, MC Raj Gupta, MD Randy L. Hammill, LTC, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Ongoing	

Study Objective: The primary study objective is to evaluate, in a cooperative group setting, the difference in survival, time to treatment failure and toxicity of two curative approaches to the treatment of patients with localized, intermediate or high grade, non-Hodgkin's lymphoma. The first treatment approach is chemotherapy using Cyclophosphamide, Doxorubicin, Vincristine and Prednisone (CHOP) for eight cycles. The second uses CHOP for three cycles followed by involved field radiation therapy.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for the reporting period: None.

Progress: One patient enrolled in study with no problems encountered this period. Study is closed to patient accrual.

DETAIL SUMMARY SHEET

Date: 9 Sep 97	**Protocol**	91-55	**Status:** Ongoing
Title:	SWOG 9013 A prospective randomized comparison of combined modality therapy for squamous carcinoma of the esophagus: Chemotherapy plus surgery alone for patients with local regional disease. Phase III intergroup		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Kenneth I. Fink, LTC, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Oncology		**Associate Investigators:** Robert D. Vallion, LTC, MC Robert A. Avery, MAJ, MC Raj Gupta, MD	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Ongoing	

Study Objective: To compare, using a prospective controlled randomized study design, the outcomes of therapy of surgery alone, versus pre- and post-operative chemotherapy and surgery for patients with local regional esophageal cancer. Outcome is defined as survival and relapse pattern. To assess the toxicities of a multimodality approach to esophageal carcinoma involving systemic chemotherapy and surgery. The toxicities of surgical resection, as initial therapy or following chemotherapy will be assessed as operative morbidity and mortality. To compare the local and distinct control rates with the two approaches and to define the pattern of failure. To compare the impact on overall and disease free survival of multimodality therapy with surgery alone.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for reporting period: None.

Progress: One patient is enrolled on this study and no problems have been encountered this period. Effective 30 Nov 95 this protocol was closed to patient accrual.

DETAIL SUMMARY SHEET

Date: 9 Sep 97	**Protocol**	91-69	**Status:** Ongoing
Title:	SWOG 9111 (EST-1690) Post-operative adjuvant interferon alpha-2 in resected high risk primary and regionally metastatic melanoma, intergroup		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Kenneth I. Fink, LTC, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Oncology/Pathology		**Associate Investigators:** Robert D.Vallion, LTC, MC Robert A. Avery, MAJ, MC Raj Gupta, MD Randy L. Hammill, LTC, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Ongoing	

Study Objective: To establish the efficacy of 1 year at maximally tolerable dosages (IV and SC) interferon alpha-2 as an adjuvant to increase the disease free interval and overall survival in patients at high risk for recurrence after definitive surgery for deep primary lesions or after regional lymph node recurrence. To evaluate the efficacy and tolerance of long-term interferon alpha-2 at 3 MU/d (Sc TIW) as an adjuvant to increase the disease-free survival and overall survival of patients at high risk for recurrence after definitive surgery for deep primary lesions or after regional lymph node recurrence with melanoma, in comparison to 1 year of treatment of maximally tolerable dosages.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled to date: No patients enrolled.

Progress: NA

DETAIL SUMMARY SHEET

Date: 9 Sep 97	**Protocol**	92-6	**Status:** Ongoing
Title:	SWOG 9008 Trial of adjuvant chemoirradiation after gastric reaction for adenocarcinoma, Phase III		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Kenneth I. Fink, LTC, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Oncology/Pathology		**Associate Investigators:** Robert D. Vallion, LTC, MC Robert A. Avery, MAJ, MC Raj Gupta, MD Randy L. Hammill, LTC, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Ongoing	

Study Objective: 1) A comparison of overall and disease free survival between patients being treated with surgical resection only and those being treated with surgery plus adjuvant therapy. 2) A comparison of incidence and patterns of disease failure between surgery and surgery plus adjuvant therapy treated patients. 3) An assessment of patient tolerance of upper abdominal chemoradiation after gastric resection.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Subjects enrolled to date: No patients enrolled.

Progress: N/A

DETAIL SUMMARY SHEET

Date: 9 Sep 97	**Protocol** 92-37	**Status:** Ongoing
Title:	SWOG 9007 Cytogenetic studies in leukemia patients, ancillary	
Start Date:		**Est. Compl. Date:**
Principal Investigator(s): Kenneth I. Fink, LTC, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Medicine/Oncology, Pathology		**Associate Investigators:** Robert A. Avery, MAJ, MC Robert D. Vallion, LTC, MC Raj Gupta, MD Randy L.Hammill, LTC, MC
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Ongoing

Study Objective: To estimate the frequencies and prognostic significance of cytogenetic abnormalities in marrow or blood cells of leukemia patients prior to treatment on Southwest Oncology Group protocols and at various times in the course of their treatment. To estimate correlations between the presence of cytogenetic features and of clinical, pathophysiological, cellular, or molecular characteristics in these patients. To provide quality control for all Southwest Oncology Group cytogenetic data.

Technical Approach: Therapy will follow schema outlined in SWOG protocol

Subjects enrolled during this reporting period: Two.

Progress: Two patients are enrolled in this study with no problems encountered. Pathology specimens, for the most recent enrolled patient, were submitted for review.

DETAIL SUMMARY SHEET

Date: 9 Sep 97	**Protocol**	92-39	**Status:** Ongoing
Title:	SWOG 9139 Adjuvant therapy of primary osteogenic sarcoma, Phase II		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Kenneth I. Fink, LTC, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Oncology, Pathology		**Associate Investigators:** Robert D. Vallion, LTC, MC Robert A. Avery, MAJ, MC Raj Gupta, MD Randy L. Hammill, LTC, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Ongoing	

Study Objective: To estimate the time to treatment failure and survival rate of the three drug combination adriamycin, cisplatin, and ifosfamide as adjunctive treatment of osteosarcoma of the extremity. To evaluate histopathologic tumor necrosis following preoperative adriamycin, cisplatin, and ifosfamide. To assess the feasibility of determining histopathologic tumor necrosis in a cooperative e group setting. To assess the influence of clinical prognostic variables on disease outcome. To assess the toxicity of this regimen.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Subjects enrolled to date: There are no patients enrolled in this study.

Progress: NA

DETAIL SUMMARY SHEET

Date:	Protocol:	Status:
9 Sep 97	92-48	Ongoing

Title:	SWOG 9054 Ancillary Bone Mineral Density Study in Premenopausal Women on EST 5188
Start Date:	**Est. Compl. Date:**
Principal Investigator(s): Kenneth I. Fink, LTC, MC	**Facility:** Eisenhower Army Medical Center
Department/Service: Medicine/Oncology/Pathology	**Associate Investigators:** Robert A. Avery, MAJ, MC Robert D. Vallion, LTC, MC Raj R. Gupta, M.D. Randy L. Hammill, LTC, MC
Key Words:	
Accumulative MEDCASE Cost:	**Periodic Review Results:** Sep 97, Ongoing

Study Objective: To evaluate whether the addition of chemotherapy to radiation therapy will result in any improvement in treatment success.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for this reporting period: 0

Progress: No patients registered.

DETAIL SUMMARY SHEET

Date: 9 Sep 97	**Protocol** 92-50	**Status:** Ongoing
Title:	SWOG 9035 Randomized trial of adjuvant immunotherapy with an allogenic melanoma vaccine for patients with intermediate thickness node negative malignant melanoma (T3NOMO)	
Start Date:		**Est. Compl. Date:**
Principal Investigator(s): Kenneth I. Fink, LTC, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Medicine/Oncology/Pathology		**Associate Investigators:** Robert D. Vallion, LTC, MC Robert A. Avery, MAJ, MC Raj Gupta, MD Randy L. Hammill, LTC, MC
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Ongoing

Study Objective: To compare disease-free survival and overall survival between patients with T3NOMO malignant melanoma who receive adjuvant immunotherapy with an allogeneic melanoma vaccine versus no adjuvant treatment. To evaluate the toxicity of adjuvant immunotherapy with an allogeneic melanoma vaccine in patients with T3NOMO malignant melanoma.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Subjects enrolled during this reporting period: None.

Progress: There is a total of three patients enrolled in this study. All patients are doing well with no problems encountered.

DETAIL SUMMARY SHEET

Date: 9 Sep 97	**Protocol**	92-69	**Status:** Ongoing
Title:	SWOG 9059 - Phase III Comparison of Standard Radiotherapy *versus* Radiotherapy Plus Simultaneous Cisplatin, *versus* Split-Course Radiotherapy Plus Simultaneous Cisplatin and 5-Fluorouracil, in Patients with Unresectable Squamous Cell Carcinoma of the Head and Neck		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Kenneth I. Fink, LTC, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Oncology/Pathology		**Associate Investigators:** Robert D. Vallion, LTC, MC Robert A. Avery, MAJ, MC Raj Gupta, MD Randy L. Hammill, LTC,MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Ongoing	

Study Objective: To compare the effectiveness of standard radiation therapy alone to radiation therapy and simultaneous chemotherapy with cisplatin to split-course radiation therapy with cisplatin and 5-fluorouracil infusion in patients with unresectable Stage III and IV squamous cell carcinoma of the head and neck. Endpoints will include complete response rate, time to treatment failure, and overall survival. To compare the relative toxicities of these three treatment arms in this patient population. To compare patterns of relapse or treatment failure among these regimens. To further assess the role, timing, and success of surgery in patients achieving a response to non-operative therapy.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled during this reporting period: No patients enrolled in this study.

Progress: N/A

DETAIL SUMMARY SHEET

Date: 9 Sep 97	**Protocol**	93-8	**Status:** Ongoing
Title:	SWOG 9133 - Randomized Trial of Subtotal Nodal Irradiation versus Doxorubicin Plus Vinblastine and Subtotal Nodal Irradiation for Stage I-IIA Hodgkin's Disease, Phase III		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Kenneth I. Fink, LTC, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Oncology		**Associate Investigators:** Robert D. Vallion, LTC, MC Raj R. Gupta, M.D. Robert A. Avery, MAJ, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Ongoing	

Study Objective: To compare the ability of two treatment regimens (radiation therapy alone or radiation plus chemotherapy), one of which will be chosen to treat the cancer. This study will also determine whether these treatments have any effect on the patients disease free survival, and whether the effects of treatment are different for different people based on age, gender, type of disease and number of disease sites.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for this reporting period: 0

Progress: No patients registered.

DETAIL SUMMARY SHEET

Date: 9 Sep 97	**Protocol**	93-19	**Status:** Ongoing
Title:	SWOG 9003 - Fludarabine for Waldenstrom's Macroglobulinemia (WM): A Phase II Pilot Study for Untreated and Previously Treated Patients		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Kenneth I. Fink, LTC, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Oncology/Pathology		**Associate Investigators:** Robert A. Avery, MAJ, MC Raj R. Gupta, M.D. Robert D. Vallion, LTC, MC Randy L. Hammill, LTC, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Ongoing	

Study Objective: The objective of this study is to find out how well patients respond and how well patients respond and how long their response lasts when treated with Fludarabine. Fludarabine is now being evaluated to determine its benefits and effectiveness on Waldenstrom's Macroglobulinemia. We want to learn more about this disease and how long it can be observed without chemotherapy.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for this reporting period: 0

Progress: N/A

DETAIL SUMMARY SHEET

Date: 9 Sep 97	Protocol 93-21	Status: Ongoing
Title:	SWOG 9201 - Phase III Trial to Preserve the Larynx: Induction Chemotherapy & Radiation Therapy vs. Concomitant Chemotherapy & Radiation Therapy vs Radiation Therapy	
Start Date:		**Est. Compl. Date:**
Principal Investigator(s): Kenneth I. Fink, LTC, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Medicine/Oncology/Pathology		**Associate Investigators:** Robert A. Avery, MAJ, MC Raj R. Gupta, M.D. Robert D. Vallion, LTC, MC Randy L. Hammill, LTC, MC
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Ongoing

Study Objective: The objective of this study is to try to preserve the larynx by using a non-surgical treatment. It involves assigning patients with larynx cancers to receive either radiation or radiation plus chemotehrapy.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for this reporting period: 0

Progress: N/A

DETAIL SUMMARY SHEET

Date: 9 Sep 97	**Protocol:** 93-22	**Status:** Ongoing
Title:	SWOG 9205 - Central Prostate Cancer Serum Repository Protocol	
Start Date:		**Est. Compl. Date:**
Principal Investigator(s): Kenneth I. Fink, LTC, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Medicine/Oncology/Pathology		**Associate Investigators:** Robert D. Vallion Robert A. Avery, MAJ, MC Raj R.Gupta, M.D. Randy L. Hammill, LTC, MC
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Ongoing

Study Objective: To serve as a repository for serum of patients with prostate cancer entered onto Southwest Oncology Group approved studies. The purpose of this activity is to provide the opportunity for study of new or existing markers or other tests in a prospective or retrospective fashion in order to test their usefulness as diagnostic or management tools in prostate cancer at all stages.

Technical Approach: As outlined in SWOG protocol.

Number of subjects enrolled for this reporting period: 0

Progress: No patients registered.

DETAIL SUMMARY SHEET

Date: 9 Sep 97	**Protocol**	93-28	**Status:** Ongoing
Title:	SWOG 9158 - Evaluation of Trans Retinoic Acid and Alpha Interferon in Patients with Squamous Cell Carcinoma of the Lung (Stage IV)		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Kenneth I. Fink, LTC, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Oncology/Pathology		**Associate Investigators:** Robert D. Vallion, LTC, MC Raj R.Gupta, M.D. Robert A. Avery, MAJ, MC Randy L. Hammill, LTC, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Ongoing	

Study Objective:To assess the response rate to trans-Retinoic Acid and Alpha Interferon used in a daily schedule for patients with advanced, well differentiated squamous cell carcinoma of the lung. To further define the qualitative and quantitative toxicities of this regimen administered to this patient population in a Phase II study.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled during this reporting period: 0

Progress: No patients registered.

DETAIL SUMMARY SHEET

Date: 9 Sep 97	**Protocol**	93-29	**Status:** Ongoing
Title:	SWOG 9216 - A Randomized Phase III Study of CODE Plus Thoracic Irradiation *versus* Alternating CAV and EP for Extensive Stage Small Cell Lung Cancer		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Kenneth I. Fink, LTC, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Oncology/Pathology		**Associate Investigators:** Robert D. Vallion, LTC, MC Raj R. Gupta, M.D. Robert A. Avery, MAJ, MC Randy L. Hammill, LTC, Mc	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Ongoing	

Study Objective: To determine whether the CODE regimen plus thoracic irradiation is superior to standard alternating CAV and EP in the treatment of extensive stage small cell lung cancer in terms of: overall survival, time to disease progression, response rate, response duration, and quality of life.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled during this reporting period: 0

Progress: No patients registered.

DETAIL SUMMARY SHEET

Date: 9 Sep 97	**Protocol**	93-43	**Status:** Ongoing
Title:	SWOG 9126 - A Controlled Trial of Cyclosporine as a Chemotherapy-Resistance Modifier in High Risk Acute Myeloid Leukemia, Phase III		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Kenneth I. Fink, LTC, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Oncology		**Associate Investigators:** Robert D. Vallion, LTC, MC Raj R.Gupta, M.D. Robert A. Avery, MAJ, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Ongoing	

Study Objective: To compare the complete remission rate and duration of survival in patients with high-risk acute myeloid leukemia (AML), when treated with either chemotherapy (ara-C/Daunomycin) alone, or chemotherapy plus the resistance modifier cyclosporine-A (CyA): To estimate the frequency of p-glycoprotein expression and the correlation with prognosis in patients with relapsed AML, primary refractory AML, and secondary AML; to compare the frequency and severity of toxicity of the two treatment regimens; and to investigate the relationship between response to treatment and the blood levels of cyclosporine-A and daunorubicin achieved.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled during this reporting period: 0

Progress: No patients registered.

DETAIL SUMMARY SHEET

Date: 9 Sep 97	**Protocol**	93-53	**Status:** Ongoing
Title:	SWOG 9221 - Phase III Double-Blind Randomized Trial of 13-Cis Retinoic Acid (13-cRA) to Prevent Second Primary Tumors (SPTs) in Stage I Non-Small Cell Lung Cancer		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Kenneth I.Fink, LTC, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Oncology		**Associate Investigators:** Robert D. Vallion, LTC, MC Raj R. Gupta, M.D. Robert A. Avery, MAJ, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Ongoing	

Study Objective: To compare daily oral administration of 13-Cis Retinoic Acid against placebo in preventing new primary lung tumors from patients having had surgical treatment of a Stage I non-small cell lung tumor.

Technical Approach: As outlined in SWOG protocol.

Number of subjects enrolled during this reporting period: 0

Progress: A total of three patients are enrolled in this this study. One patient chose to come off study. Protocol closed to patient accrual.

DETAIL SUMMARY SHEET

Date: 9 Sep 97	**Protocol**	93-55	**Status:** Closed
Title:	SWOG 9210 - A Phase III Randomized Trial of Combination Therapy for Multiple Myeloma Comparison of (1) VAD-P to VAD-P/Quinine for Induction; (2) Randomization of Prednisone Dose Intensity for Remission Maintenance		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Kenneth I. Fink, LTC, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Oncology/Pathology		**Associate Investigators:** Robert D. Vallion, LTC, MC Raj R. Gupta, M.D. Robert A. Avery, MAJ, MC Randy L. Hammill, LTC, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Closed	

Study Objective: To compare the effectiveness of the VAD-P chemotherapy regimen when administered alone or in combination with the chemosensitizer quinine. It will evaluate the chemosensitizing potential of quinine to reverse drug resistance.

Technical Approach: As outlined in SWOG protocol.

Number of subjects enrolled duirng this reporting period: 0

Progress: No patients registered. Protocol closed to patient accrual.

DETAIL SUMMARY SHEET

Date: 9 Sep 97	**Protocol**	94-16	**Status:** Closed
Title:	SWOG 9303: Phase III Study of Radiation Therapy, Levamisole and 5-Fluorouracil versus 5-Fluorouracil and Levamisole in Selected Patients with Completely Resected Colon Cancer		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Kenneth I. Fink, LTC, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Oncology/Pathology		**Associate Investigators:** Robert D. Vallion, LTC, MC Raj R. Gupta, M.D. Robert A. Avery, MAJ, MC Randy L. Hammill, LTC, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Closed	

Study Objective: To determine whether 5FU, levamisole and radiation therapy results in superior overall survival when compared to 5FU and levamisole without radiation therapy in the management of patients with completely resected pathologic stage (T4bNo-2) colon cancer and selected patients with (T3N1-2) colon cancer. Disease free survival, patterns of failure and toxicity will also be evaluated.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for this reporting period: 0

Progress: No patients registered. Protocol closed to patient accrual.

DETAIL SUMMARY SHEET

Date: 9 Sep 97	**Protocol**	94-21	**Status:** Ongoing
Title:	SWOG 9005: Double Blind Randomized Trial of the Anti-Progestational Agent Mifepristone in the Treatment of Unresectable Meningioma, Phase III		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Kenneth I. Fink, LTC, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Oncology/Pathology		**Associate Investigators:** Robert D. Vallion, LTC, MC Raj R. Gupta, M.D. Robert A. Avery, MAJ, MC Randy L. Hammill, LTC, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Ongoing	

Study Objective: To find out whether patients will respond and how long their response lasts if treated with the experimental antiprogestational agent mifepristone.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for this reporting period: 0

Progress: N/A.

DETAIL SUMMARY SHEET

Date: 9 Sep 97	**Protocol**	94-22	**Status:** Ongoing
Title:	SWOG 9250: Phase III Intergroup Prospectively Randomized Trial of Perioperative 5-FU after Curative Resection Followed by 5-FU/Levamisole for Patients with Colon Cancer		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Kenneth I. Fink, LTC, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Oncology/Pathology		**Associate Investigators:** Robert D. Vallion, LTC, MC Raj R. Gupta, M.D. Robert A. Avery, MAJ, MC Randy L. Hammill, LTC, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Ongoing	

Study Objective: To determine if adjuvant therapy with one week of continuous 5-FU given within 24 hours of a curative colon resection followed by 12 months of 5-FU/levamisole is effective in prolonging the disease free interval and increasing survival in patients with Dukes B3 or C colon cancer, when compared to patients who are treated with 5-FU/levamisole only.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for this reporting period: 0

Progress: A total of three patients are enrolled in this study with no problems encountered this period.

DETAIL SUMMARY SHEET

Date: 9 Sep 97	**Protocol**	94-23	**Status:** Ongoing
Title:	SWOG 9312: Phase II Evaluation of Cisplatin + 5FU + Radiation Therapy in Patients with Locally Advanced/Inoperable Bladder Cancer		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Kenneth I. Fink, LTC, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Oncology/Pathology		**Associate Investigators:** Robert D. Vallion, LTC, MC Raj R. Gupta, M.D. Robert A. Avery, MAJ, MC Randy L. Hammill, LTC, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Ongoing	

Study Objective: To assess the response rate and the feasibility of utilizing cisplatin + 5FU + radiation therapy in patients with locally advanced/inoperable carcinoma of the bladder. This study will also assess the qualitative and quantitative toxicities of this combination.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for this reporting period: 0

Progress: No patients registered.

DETAIL SUMMARY SHEET

Date: 9 Sep 97	**Protocol** 94-24	**Status:** Ongoing	
Title:	SWOG 9300: A Randomized Phase II Evaluation of All Trans Retinoic Acid (ATRA) with Interferon-Alfa 2a (IFNOalfa 2a) or All Trans Retinoic Acid with Hydroxyurea (H) in Patients with Newly Diagnosed Chronic Myelogenous Leukemia in Chronic Phase		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Kenneth I. Fink, LTC, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Oncology/Pathology		**Associate Investigators:** Robert D. Vallion, LTC, MC Raj R. Gupta, M.D. Robert A. Avery, MAJ, MC Randy L. Hammill, LTC, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Ongoing	

Study Objective: To find out how well patients respond and how long their response lasts when treated with either All Trans Retinoic Acid and hydroxyurea or All Trans Retinoic Acid and interferon. This study will also find out what kind of side effects these drugs cause and how often they occur; and examine the cells of the patient's bone marrow to find out if there is any connection between response to treatment and the type of cells that are identified in the bone marrow.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for this reporting period: One.

Progress: Two patients are enrolled in this study with no problems encountered this period.

DETAIL SUMMARY SHEET

Date: 9 Oct 97	**Protocol**	94-89	**Status:** Ongoing
Title:	SWOG 9208 - Health Status and Quality of Life (QOL) in Patients with Early Stage Hodgkins Disease: A companion Study to SWOG 9133, Ancillary		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Kenneth I. Fink, LTC, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Oncology/Pathology		**Associate Investigators:** Robert D. Vallion, LTC, MC Robert A. Avery, MAJ, MC Raj R. Gupta, M.D. Randy L. Hammill, LTC, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Ongoing	

Study Objective: To evaluate prospectively the health status and quality of life (QOL) of early stage Hodgkin's Disease patients receiving either subtotal irradiation or short course chemotherapy plus subtotal nodal irradiation.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for this reporting period: 0

Progress: No patients registered.

DETAIL SUMMARY SHEET

Date: 9 Oct 97	**Protocol** 94-94	**Status:** Ongoing	
Title:	SWOG 9336 - A Phase III Comparison Between Concurrent Chemotherapy Plus Radiotherapy, and Concurrent Chemotherapy Plus Radiotherapy Followed by Surgical Resection of Stage IIIA (N2) Non-Small Cell Lung Cancer		
Start Date: Dec 94		**Est. Compl. Date:**	
Principal Investigator(s): Kenneth I. Fink, LTC, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Oncology		**Associate Investigators:** Robert D. Vallion, LTC, MC Robert A. Avery, MAJ, MC Raj Gupta, MD	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Ongoing	

Study Objective: To evaluate the likelihood of response of hormone refractory, metastatic carcinoma of the prostate treated with F-FU and Roferon-A in order to assess whether this regimen should be advanced to further studies. To assess the qualitative and quantitative toxicities of this regimen administered in a phase II study.

Technical Approach: Therapy will follow schema outlined in SWOG protocol

Number of subjects enrolled during this reporting period: None.

Progress: None. Request study remain open for patients who might meet criteria.

DETAIL SUMMARY SHEET

Date: 9 Oct 97	**Protocol**	95-6	**Status:** Ongoing
Title:	SWOG 9445 - Prognostic Factor Panel to Predict Preferred Therapy for Node Positive Postmenopausal Breast Cancer Patients (CAF vs Tamoxifen) (A Companion Protocol to SWOG 8814)		
Start Date: Feb 95		**Est. Compl. Date:**	
Principal Investigator(s): Kenneth I. Fink, LTC, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Oncology/Pathology		**Associate Investigators:** Robert D. Vallion, LTC, MC Robert A. Avery, MAJ, MC Raj Gupta, MD Randy L. Hammill, LTC, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Ongoing	

Study Objective: To correlate a panel of markers with clinical outcome and responsiveness to adjuvant therapy of node positive post menopausal breast cancer patients who participated in SWOG 8814, and to confirm the results of the CALGB study, CALGB 8541, which suggested that c-erb B-2 expression is a strong predictor of the efficacy of CAF based adjuvant chemotherapy.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for this reporting period: No patients enrolled in this study.

Progress: NA

DETAIL SUMMARY SHEET

Date: 9 Oct 97	**Protocol** 95-16	**Status:** Ongoing	
Title:	SWOG 9333 - A Randomized Controlled Trial of Mitoxantrone and Etoposide versus Daunomycin and Cytosine Arabinoside as Induction Chemotherapy in Patients Over Age 55 with Previously Untreated Acute Myeloid Leukemia, Phase III		
Start Date: February 1995		**Est. Compl. Date:**	
Principal Investigator(s): Kenneth I. Fink, LTC, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Oncology, Pathology		**Associate Investigators:** Robert D. Vallion, LTC, MC Robert A. Avery, MAJ, MC Raj Gupta, MD Randy L. Hammill, LTC, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Ongoing	

Study Objective: The goal of this study is to improve the complete response rate and disease-free survival in patients over age 55 by designing a remission induction regimen that will decrease toxicity and increase anti-leukemic effect compared with standard induction therapy of daunomycin and cytosine arabinoside.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled: No patients enrolled.

Progress: NA.

DETAIL SUMMARY SHEET

Date: 9 Oct 97	Protocol: 96-25	Status: Ongoing
Title:	SWOG 9419 Tumor Tissue Biopsy for Thymidylate Synthase Expression in Patients with Colorectal Cancer Ancillary	
Start Date:		**Est. Compl. Date:**
Principal Investigator(s): Kenneth I. Fink, LTC, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Medicine/Oncology/Pathology		**Associate Investigators:** Robert D. Vallion, LTC, MC Robert A. Avery, MAJ, M C Raj R. Gupta, MD Randy L. Hammill, LTC, MC
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Ongoing

Study Objective: To measure thymidylate synthase (TS) expression by polymerase chain reaction in tumor biopsies prior to initiation of fluorinated pyrimidine based therapy in patients with disseminated colorectal cancer and correlate tumor responses with level of TS expression.

Technical Approach: The Southwest Oncology Group enters over 600 patients per year in postoperative adjuvant trials for poor-prognosis colon (Stage III) and rectal cancers (Stages II and III). By quantitating TS expression in primary colorectal tumors and their draining lymph nodes, following these patients for recurrence and survival after adjuvant therapy, and correlating the results through the Suthwest Oncology Group Statistical Office, it might be possible to better predict who is at greater risk of relapse and death on 5-FU regimens based on TS levels.

Number of subjects enrolled in study this reporting period. 0

Progress: No patients are enrolled.

DETAIL SUMMARY SHEET

Date: 9 Oct 97	Protocol: 97-34	Status: Ongoing
Title:	SWOG 9400 Treatment of Adult Acute Lymphoblastic Leukemia: Phase II Trials of an Induction Regimen Including PEG-L-Asparaginase, In Previously Untreated Patients, Followed by Allogeneic Bone Marrow Transplantation or Further Chemotherapy in First Complete Remission	
Start Date:		**Est. Compl. Date:**
Principal Investigator(s): Kenneth I. Fink, LTC, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Medicine/Oncology/Pathology		**Associate Investigators:** Robert D. Vallion, LTC, MC Robert A. Avery, MAJ, M C Raj R. Gupta, MD Randy L. Hammill, LTC, MC
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Ongoing

Study Objective: To determine how well patients respond and how long their response last when treated with a combination of drugs and possibly, bone marrow transplantation with radiation therapy.

Technical Approach: The first phase (induction) patients will receive allopurinol, daunorubicin, vincristine, prednisone, PEG-L-asparaginase, acetominophen and Bactrim. Additional therapy will be given those who have CNS leukemia. Second phase (consolidaiton) will receive cyclophosphamide, cytosine arabinoside (ara-C), 6-mercaptopurine and methotrexate. The third phase (post consolidation) patients will receive either standard maintenance therapy or an allogeneic bone marrow transplant. In the bone marrow transplant very high doses of chemotehrapy are given along with bone marrow that is obtained from a matched relative. It is riskier and may be complicated by a reaction of the donor's bone marow against the patient, which is called graft versus host disease.

Number of subjects enrolled in study this reporting period. One.

Progress: A total of one patient has been enrolled with no problems. Patient has been transferred.

DETAIL SUMMARY SHEET

Date:	13 Oct 97	**Protocol**	94-83	**Status:**	Ongoing
Title:	Impact of the Threat of War on Military Children.				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): MAJ Nancy A. Ryan-Wenger			**Facility:** USA MEDDAC, FT Campbell, KY		
Department/Service: Nursing			**Associate Investigators:**		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 97, Ongoing		

Study Objective: The purpose of this study is to find out how well military children are handling this stressor in their lives and whether health professionals should be doing something more to help children deal with it. In a pilot study, several children have said that "no one has ever asked for my opinion before". This is an opportunity for the child to talk about this subject to someone who is objective and truly interested in what he or she has to say. Also, after completing the questionnaire, the child will become aware of the variety of coping strategies that he/she can use to deal with this and other life's stressors.

Technical Approach: There are questions about the child's thoughts and feelings, about worries and fears, and a few questions about what the child thinks or has heard about war. At any time during the interview that the child appears to be upset, the interview will be stopped. The interview will be tape-recorded so tht the interviewer can focus on the child and not extensive notetaking. ID numbers and not names will be used on all forms to protect the child's confidentiality.

Number of subjects enrolled: Civilians 48; Active Duty 18; Reservists 25.

Progress: PI would like to have at least 30 subjects in the Active Duty and Reservist groups. Should be able to accomplish this goal in the next six months.

Problems Encountered: Recruitment of subjects has been slower than anticipated due to long distance between data collection sites and the University where the PI is located.

SUMMARY DETAIL SHEET

Date: 9 Sep 97	**Protocol**	93-33	**Status:** Closed
Title:	Vocal Cord Function and Voice Quality Evaluation of Active Duty U.S. Army Drill Instructors		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Pearline McKenzie, CPT, MC		**Facility:** USA MEDDAC, Ft Jackson, SC	
Department/Service: Nursing		**Associate Investigators:**	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Closed	

Objective: To document the laryngeal pathology and record the acoustic effects of acute voice abuse in active duty US Army drill instructors during periods of intense training.

Technical Approach: Subjects will be chosen for videostroboscopy and acoustic analysis preceding and during the early phases of small unit training.

Number of subjects enrolled for the reporting period: None

Progress: None. Study closed.

DETAIL SUMMARY SHEET

Date: 30 Sep 97	**Protocol:** 95-41	**Status:** Completed
Title:	An Assessment of Knowledge, Attitudes, and Behavior of the Female Basic Recruit in the US Army Concerning Sexually Transmitted Diseases	
Start Date: 23 Oct 95		**Est. Compl. Date:** Aug 96
Principal Investigator(s): LTC Joan Eitzen		**Facility:** USA MEDDAC, FT Jackson, SC
Department/Service: Nursing/Preventive Medicine		**Associate Investigators:**
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Completed

Study Objective: The main objective of this study is to assess the knowlege, attitudes and preventive behaviors of new female recruits that may put them at risk for sexually transmitted diseases using a self administered survey. This would provide a profile of the knowledge, attitudes and behaviors of the women currently entering the military. The results of this descriptive study would help educators in the Army to develop health education interventions and materials for women in the military in an effort health and impact the high rates of STDs and unintended pregnancies in the military.

Technical Approach: The nurse involved in the chlamydia study will collect urine from 2,000 incoming female basic recruits at FT Jackson. Urine collection and questionnaire adminstration will be integrated into routine medical in-processing of recruits to minimize disruption of recruit training. Informed consent forms will not be signed for participation. The study will be completely anonymous.

Number of subjects enrolled during this period: 0. Study completed.

DETAIL SUMMARY SHEET

Date: 13 Oct 97	**Protocol**	94-19	**Status:** Closed
Title:	Carbohydrate Deficient Transferrin as a Measure of Alcohol Use Among US Army Personnel.		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Kim J. Zagorski, MAJ, MC		**Facility:** USA MEDDAC, FT Benning, GA	
Department/Service: Family Practice		**Associate Investigators:** CPT Kelly A. Murray, MC John P. Allen, PhD Sidney Levine, PhD MAJ Marsha L. Bloodworth, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Closed	

Study Objective: To determine if a substance in blood call "carbohydrate deficient transferrin" can accccurately measure past use of alcohol and how results of this test relate to other laboratory and interview measures of drinking. Subjects are asked to submit a small blood sample which is analyzed by a laboratory. They will complete questionnaires and interviews on their use of alcohol and problems that drinking may be causing them. All procedures with the subject are expected to be completed in a single visit.

Technical Approach: Three hundred subjects will be enrolled in the study. The sample will be stratified on this basis of self-reported time since last drink. One hundred twenty-five subjects will have consumed alcohol within the seven days before assessment; one hundred twenty-five between eight and fourteen days prior to assessment; and fifty between fifteen and twenty-one days before assessment. Subjects will selected sequentially from inidviduals receiving the ADAPCP evaluation and in proportion to the required three subsample sizes. Two research assistants, trained by staff from the University of Connecticut in the Coordinating Center for Project MATCH, will conduct all assessments.

Number of Subjects Enrolled to Date: 23

Progress: None.

Problems Encountered: Slow enrollment. Study closed.

DETAIL SUMMARY SHEET

Date: 9 Sep 97	**Protocol:** 97-31	**Status:** Ongoing
Title: IND Application for "Methacholine Inhalation"		
Start Date:	**Est. Compl. Date:**	
Principal Investigator(s): Stephen M. Salerno, CPT,MC	**Facility:** USA MEDDAC, FT Benning, GA	
Department/Service: Medicine/Pulmonary	**Associate Investigators:**	
Key Words:		
Accumulative MEDCASE Cost:	**Periodic Review Results:** Sep 97, Ongoing	

Study Objective: To obtain methacholine in bulk (30-50 100mg vials/month) to provide rapid diagnostic services to soldiers until Methapharm Corporation is able to get FDA approval to market their product directly to the United States.

Technical Approach: Medication will be prepared by mixing one vial of 100mg powdered methacholine chloride with 4cc of normal saline. This is solution #5. Then mix 1cc of #5 solution with 1.5cc normal saline to make a 10mg/mL solution. This is solution #4. Mix 0.5cc of solution #5 with 4.5cc normal saline to make a 2.5mg/mL solution. This is solution #3. Mix 0.5cc of solution #3 with 4.5cc normal saline to make a 0.25mg/mL solution. This is solution #2. Then mix 0.5cc of solution #2 with 4.5cc normal saline to make a 0.025 mg/mL solution. This is solution #1. Perform a flow volume loop to establish a baseline forced vital capacity and forced expiratory volume. Administer 5 breaths of norml saline and perform flow volume loop ad deermie f herehas beena 20% decrease the FEV1. Repeat step 2 and 3 starting with solution #1 and prgresin through #5. Perform flow volume loops after each albuterol nebulizer treatment until the FEV1 returns within 5% of baseline. Monitor heart rate and oxygen saturation with pulse oximeter during all bronchodilator therapy.

Progress: Study recently implemented.

DETAIL SUMMARY SHEET

Date: 9 Sep 97	**Protocol**	97-36	**Status:** Ongoing
Title:	The Effect of Colonoscopy on Serum PSA		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Bradley F. Schwartz, MAJ, MC		**Facility:** **USA MEDDAC, FT Benning, GA**	
Department/Service: Surgery/Urology		**Associate Investigators:**	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Ongoing	

Study Objective: To determine the effect colonoscopy has on serum prostate specific antigen (PSA) levels.

Technical Approach: Fifty consecutive males will obtain serum PSA determinations within 24 hours of colonoscopy. Additional PSA levels will be obtained 24 hours, seven days and one month after the procedure. Pre- and post-colonoscopy levels will be compared and it will be determined if this common procedure significantly elevates serum PSA values.

Progress: Twenty-two patients are currently enrolled. Study remains ongoing.

Problems Encountered: None.

DETAIL SUMMARY SHEET

Date: 9 Sep 97	**Protocol :** 97-37	**Status:** Ongoing	
Title:	The Effects of Salmeterol, A Long-Acting Beta-Agonist on Hyperkalemia in Nondialysis Requiring Patients with Chronic Renal Failure		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Dana K. Renta, CPT, MC		**Facility:** USA MEDDAC, FT Benning, GA	
Department/Service: Family Practice		**Associate Investigators:**	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Ongoing	

Study Objective: To determine whether salmeterol administration can result in significant lowering of serum potassium levels in chronic renal failure patients that do not require dialysis.

Technical Approach: Subjects will be assigned in a double-blinded fashion to both placebo and treatment rouat alternating times during the study period using an initial randomization and cross-cover design. The duration of the drug period is one week of placebo treatment, one week washout period, and one week of treatment intervention. The drug will be administered via metered dose inhaler using a spacer, after instruction from research assistant.

Progress: 10+ subjects have been enrolled.

Problems Encountered: Difficulty obtaining referrals for enrollment. One subject developed hyperkalemia secondary to a urinary tract infection and was removed from study and treated.

DETAIL SUMMARY SHEET

Date: 9 Sep 97	**Protocol** 97-40	**Status:** Ongoing
Title:	Approval of Outbreak Investigation of Hyponatremia Among Trainees	
Start Date:		**Est. Compl. Date:**
Principal Investigator(s): William P. Corr, MAJ, MC		**Facility:** USA MEDDAC, FT Benning, GA
Department/Service: Preventive Medicine		**Associate Investigators:**
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 97, Ongoing

Study Objective: This study is designed to assess the prevalence and risk factors associated with exertional hyponatremia in basic trainees.

Technical Approach: After obtaining informed consent, participants will complete a survey regarding fluid intake, general information, and heat related symptoms. After which, all participants will have blood drawn twice to obtain serum sodium, liver enzymes, and CPK levels as well as submit a urine sample. All participants will be males from the Fort Benning Training Brigade.

Progress: Data collected from 300 patients. 18,000+ data points entered in data base. Study continues.

Problems Encountered: Difficulty entering data. No adverse reactions.

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